Petition

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Petitioners,

v.

ANNE M. GORSUCH, ADMINISTRATOR,
AND ENVIRONMENTAL PROTECTION AGENCY,
Respondents.

JOINT PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

EDWARD W. WARREN*
ROBERT F. VANVOORHEES
JOHN S. HAHN
KIRKLAND & ELLIS
1776 K Street, N.W.
Washington, D.C. 20006
(202) 857-5000

Counsel for American Petroleum Institute and Member Company Petitioners

JOHN H. PICKERING
WILLIAM H. LEWIS, JR.
DAVID R. JOHNSON
WILMER, CUTLER & PICKERING
1666 K Street, N.W.
Washington, D.C. 20006

Counsel for Chemical Manufacturers Association

Of Counsel:
STARK RITCHIE
DAVID T. DEAL
American Petroleum Institute

EDMUND B. FROST
Chemical Manufacturers Association

November 10, 1981

**Counsel of Record*

Additional counsel listed inside cover.

J. MARSHALL COLEMAN
ATTORNEY GENERAL OF VIRGINIA
ROGER L. CHAFFE
ASSISTANT ATTORNEY GENERAL
Suite 308
11 South 12th Street
Richmond, Virginia 23219

Counsel for the Commonwealth of Virginia, ex rel. the State Air Pollution Control Board

BERNARD J. REILLY
1007 Market Street
Wilmington, Delaware 19898

Counsel for E. I. du Pont de Nemours & Company

WILKES C. ROBINSON
J. SCOTT BROWN
GULF COAST & GREAT PLAINS
LEGAL FOUNDATION
127 West 10th Street
Room 1022
Kansas City, Missouri 64105

Counsel for St. Louis Regional Commerce and Growth Association

JAN ERIC CARTWRIGHT
ATTORNEY GENERAL OF OKLAHOMA
NEAL LEADER
ASSISTANT ATTORNEY GENERAL
112 State Capitol Building
Oklahoma City, Oklahoma 73105

Counsel for State of Oklahoma

QUESTIONS PRESENTED

The questions presented for review by this Court are:

1. Whether the court below correctly construed § 307(d)(8) of the Clean Air Act as excusing the Environmental Protection Agency's violation of mandatory statutory requirements, with the practical effect of undermining any opportunity for meaningful judicial review of the Agency's decisions.

2. Whether the court below correctly construed § 109 of the Clean Air Act as imposing no substantive limitations on the Environmental Protection Agency's discretion to establish national ambient air quality standards, and if so, whether that provision constitutes an excessively sweeping and unfettered delegation of legislative authority in violation of the Constitution.

LIST OF PARTIES

The parties before the court of appeals included the American Petroleum Institute and 15 of its member companies,[1] the Chemical Manufacturers Association and four of its member companies,[2] the Commonwealth of Virginia, *ex rel.* the State Air Pollution Control Board, E. I. du Pont de Nemours & Company, the St. Louis Regional Commerce and Growth Association, the State of Oklahoma and the City of Houston.[3]

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[1] Atlantic Richfield Company, Continental Oil Company, Exxon Company U.S.A., Getty Oil Company, Gulf Oil Corporation, Grace Petroleum Corporation, Kerr-McGee Corporation, Mobil Oil Corporation, Pennzoil Company, Shell Oil Company, Standard Oil Company (Indiana), The Standard Oil Company (Ohio), Texaco Inc., Union Oil Company of California, and Witco Chemical Corporation.

[2] American Cyanamid Company, Diamond Shamrock Corporation, Ethyl Corporation, and Northern Petrochemical Company.

[3] The parties below also included the Natural Resources Defense Council, the Delaware Valley Citizens Committee for Clean Air, Inc., the Connecticut Lung Association, Inc., the American Lung Association, and the Sierra Club.

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JOINT PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The American Petroleum Institute and its member company petitioners,[4] the Chemical Manufacturers Association, the Commonwealth of Virginia, *ex rel.* the State Air Pollution Control Board, E. I. du Pont de Nemours & Company, the St. Louis Regional Commerce and Growth Association, and the State of Oklahoma respectfully petition for a Writ of Certiorari to review the decision of the United States Court of Appeals for the District of Columbia Circuit in the case of *American Pet-*

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[4] Continental Oil Company, Exxon Corporation, Getty Oil Company, Gulf Oil Corporation, Grace Petroleum Corporation, Kerr-McGee Corporation, Mobil Oil Corporation, Pennzoil Company, Shell Oil Company, Standard Oil Company (Indiana), Texaco Inc., and Witco Chemical Corporation.

roleum Institute v. *Costle, et al.*, No. 79-1104, and consolidated cases.[5]

OPINIONS BELOW

The opinion of the court of appeals is reported at ____ F.2d ____, slip op. (D.C. Cir. 1981) (Petitioners' Appendix A). A previous opinion of the court ordering corrections to the record is reported at 609 F.2d 20 (D.C. Cir. 1979) (Petitioners' Appendix B). The Environmental Protection Agency's statement of basis and purpose for the ozone standard is reported at 44 Fed. Reg. 8202 (1979) (Petitioners' Appendix C).

JURISDICTION

The judgment of the court of appeals was entered on September 3, 1981. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

This case involves review of the national ambient air quality standard for ozone, 44 Fed. Reg. 8202 (1979), codified at 40 C.F.R. § 50.9, as promulgated pursuant to the Clean Air Act, 42 U.S.C. §§ 7401 *et seq.* This case also involves application of § 8 of the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA), 42 U.S.C. § 4365, the Federal Advisory Committee Act, 5 U.S.C. app. §§ 3 *et seq.*, and Article I, § 1 of the United States Constitution, which provides that "All legislative Powers herein granted shall be vested in a Congress. . . ." Pertinent provisions of the applicable regulation and statutes are appended to this Petition (Petitioners' Appendix[6] D).

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[5] Pursuant to Supreme Court Rule 40.3, the case caption on this Petition has been changed because Anne M. Gorsuch has replaced Douglas M. Costle as Administrator of the Environmental Protection Agency. A list of the corporate petitioners' parent companies, subsidiaries and affiliates is being filed as a Supplemental Appendix, pursuant to Supreme Court Rule 28.1.

STATEMENT OF THE CASE

A. Statutory Background

The Clean Air Act, 42 U.S.C. §§ 7401 *et seq.*, establishes a comprehensive scheme for the regulation of air pollutants that threaten public health or welfare. The paramount provisions of the Act are §§ 108 and 109, P.A. 103a-104a, which authorize the Administrator of the Environmental Protection Agency (EPA) to promulgate national ambient air quality standards establishing the maximum permissible levels of pollutants in the ambient (outdoor) air. Section 110, 42 U.S.C. § 7410, requires the states to prepare and implement whatever pollution control measures are necessary to ensure timely attainment of the national standard.

This Court twice has reviewed provisions of § 110 governing implementation of national ambient air quality standards, *Train* v. *NRDC*, 421 U.S. 60 (1975), and *Union Electric Co.* v. *EPA*, 427 U.S. 246 (1976), but never has construed the seminal standard-setting provisions of §§ 108 and 109, which are at issue in this case.[7]

Section 108(a)(2) directs the Administrator to prepare an "air quality criteria" document which "accurately reflect[s] the latest scientific knowledge" about the effects of selected pollutants on public health and welfare. P.A. 103a. Section 109(a) authorizes the Administrator to promulgate "primary" national ambient air quality standards, which are described in § 109(b)(1) as standards "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." P.A. 104a. Apart from the provisions of §§ 108 and 109, the statutory text provides no express guidance or limits on what factors the Administrator may consider in setting such standards.[8]

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[6] Hereinafter "P.A."

[7] The Court also granted writs of certiorari in Brown v. EPA, 521 F.2d 827 (9th Cir. 1975) and related cases, in which states challenged EPA's authority to require adoption of motor vehicle inspection programs to implement the previous ozone standard. The Court declined to review these cases on the merits, however, after EPA conceded that the disputed regulations were invalid. EPA v. Brown, 431 U.S. 99 (1977).

In 1977, Congress provided for an independent Science Advisory Board to which EPA was required to submit for review and comment all proposed criteria documents and all proposed standards, along with supporting scientific information, under the Clean Air Act and all other statutes administered by EPA.[9] Review of proposed criteria documents and standards

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[8] Section 307(d) prescribes administrative procedures applicable to setting ambient air quality standards. P.A. 106a-112a.

[9] Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA), § 8, 42 U.S.C. § 4365, P.A. 112a-113a.

ERDDAA requires independent scientific review of regulations issued not only under the Clean Air Act, but also under the Federal Water Pollution Control Act, the Resource Conservation and Recovery Act of 1976, the Noise Control Act, the Toxic Substances Control Act, the Safe Drinking Water Act, and "any other authority of the Administrator." *Id.* at 113a.

In 1976, Congressional committees had found serious deficiencies in EPA's research on the health effects of air pollution, including an apparent tendency to stretch interpretations to support EPA's regulatory positions. Staffs of the House Interstate and Foreign Commerce Committee and the House Science and Technology Committee, 94th Cong., 2d Sess., Report on Joint Hearings on the Conduct of the Environmental Protection Agency's "Community Health and Environmental Surveillance System" (CHESS) Studies (Comm. Print 1976). As a result of this investigation, § 8 of ERDDAA was enacted in 1977. H.R. Rep. No. 722, 95th Cong., 1st Sess. 16-18 (1977).

In the 1977 Clean Air Act Amendments, Congress also required independent scientific review of all air quality criteria documents and standards on an ongoing basis. 42 U.S.C. § 7409(d), P.A. 104a-105a. The responsibility by the Science Advisory Board was envisioned as a major reform of the standard-setting process. The Board's comments would provide the Administrator with authoritative scientific advice, independent of the Agency's own staff, and thereby improve the quality of EPA's standards.[10] At the same time, the Board—composed of persons "qualified by education, training and experience to evaluate scientific and technical information" (42 U.S.C. § 4365(b))—would provide an evaluation of proposed rules that would facilitate and enhance judicial review of EPA's decisions.[11]

The Clean Air Act Amendments of 1977 required EPA to revise, "as may be appropriate," all existing air quality criteria and standards. 42 U.S.C. § 7409(d)(1), P.A. 104a. In that year, EPA initiated rulemaking proceedings to review the ozone standard at issue in this case.[12]

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for conducting independent scientific review as required by ERDDAA and the Clean Air Act is held now by the Clean Air Scientific Advisory Committee, a subcommittee of EPA's Science Advisory Board.

[10] In passing § 8 of ERDDAA, Congress intended for the Science Advisory Board "to review conflicting claims and advise the Administrator on the adequacy and reliability of the technical basis for rules and regulations." H.R. Rep. No. 722, 95th Cong., 1st Sess. 16 (1977).

[11] Prior to the enactment of ERDDAA, courts repeatedly had noted the difficulties posed for appellate judges charged with reviewing scientific and technical issues underlying EPA regulations. *See* International Harvester Co. v. Ruckelshaus, 478 F.2d 615, 647-48 (D.C. Cir. 1973), Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 402 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974). *Compare* Ethyl Corp. v. EPA, 541 F.2d 1, *cert. denied sub nom.*, E.I. du Pont de Nemours & Co. v. EPA, 426 U.S. 941 (1976), concurring op. of J. Bazelon at 67 ("substantive review of mathematical and scientific evidence by technically illiterate judges is dangerously unreliable"), with concurring op. of J. Leventhal, at 68 ("[o]ur present system of review assumes judges will acquire whatever technical knowledge is necessary as background for decision of the legal questions").

[12] Ozone (O_3) is a form of oxygen that can be formed in the ambient air from chemical reactions involving organic compounds. Joint Appendix (from the proceedings in the court of appeals; hereinafter "J.A.") Ex. 1 at

B. EPA Ozone Rulemaking

Throughout the ozone rulemaking, EPA's actions raised questions about its willingness to comply with prescribed statutory requirements, and to review the existing standard with an open mind. EPA began the proceedings, not by seeking Science Advisory Board review of a draft criteria document, but rather by convening another group of advisers to recommend a conclusion on the ultimate issue of the rulemaking, *i.e.*, "the translation of health data into an ambient air quality standard." P.A. 23a-24a. This group, which EPA named its "Advisory Panel on Health Effects of Photochemical Oxidants," was empanelled and met without public notice. The Panel was chaired by a former EPA official who also was serving as the public spokesman for an interest group favoring no revision of the standard. J.A. 258. The Panel's Report, prepared in June, 1977 with EPA staff assistance, advocated retention of the existing standard. J.A. 259, 277-79.

3-3. Therefore, emissions of fuels and other organic compounds are controlled to reduce ambient ozone levels.

Ambient ozone also results, however, from two natural sources over which man has no control. The first is organic compounds emitted by vegetation which, like organic emissions from man-made sources, can produce ozone by chemical reaction. J.A. Ex. 1. at 4-62. A second significant natural source is the transfer to ground level of ozone from the stratosphere (J.A. Ex. 1 at 4-48), where ozone is considered beneficial in screening the earth from ultra-violet radiation.

Ambient ozone levels sometimes have been associated with temporary irritation of the respiratory tract, but have not been shown to increase mortality or to cause long-term effects in humans. J.A. 647. Consequently, a major factual issue in setting the primary ozone standard was whether EPA reasonably could interpret various scientific studies as showing a significant risk of short-term health effects at various ambient ozone levels.

The original ozone standard was denominated a "photochemical oxidant" standard when set in 1971. J.A. 57. The initial standard was set at the unrealistically stringent level of 0.08 parts per million (ppm), based on EPA's concededly mistaken reading of a single study. J.A. 440.

Only after that report was written did EPA provide the statutory Science Advisory Board with drafts of the criteria document, which were reviewed at public meetings in November, 1977 and February, 1978. The Board consistently criticized those drafts as scientifically deficient and biased in favor of an excessively stringent standard. J.A. Ex. 2. In ballots cast in March, 1978, not one of the eleven Board members was willing to advise EPA that the existing draft could be considered a "scientifically acceptable criteria document" without major revisions. J.A. 287-310. The Board's Chairman, Dr. James Whittenberger,[13] wrote: "I found the authors had responded insufficiently to many criticisms made by members of the Subcommittee and by others. The health risk assessments are largely speculative, incomplete, and heavily dependent on studies of questionable validity." J.A. 293.

After the Science Advisory Board had repeatedly criticized the scientific quality of EPA's draft criteria document, EPA terminated the Board's role in the rulemaking. Without seeking the Board's advice, EPA issued a final criteria document and proposed a barely revised standard of 0.10 ppm. J.A. 437. The proposal was based substantially on the conclusions presented in the Advisory Panel Report noted above and on the results of a "decision analysis" technique that EPA had withheld from review by the Science Advisory Board. J.A. 441.

Petitioners urged EPA to submit the proposal for review by the Science Advisory Board, as was EPA's clear duty under ERDDAA. Nevertheless, EPA refused to do so.[14] Although the proposal was not reviewed by the Science Advisory Board, it was addressed in public comments by President Carter's Regulatory Analysis Review Group, an interagency group of regulatory analysts assembled to improve the scientific quality and cost-effectiveness of major federal regulations.

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[13] Like all of the members of the Science Advisory Board, Dr. Whittenberger is a highly respected scientist, who is a Professor and the former Dean of the Harvard School of Public Health. J.A. 291-92.

[14] No practical reason prevented EPA from submitting the proposal to the Science Advisory Board. The proposal was published in the Federal Register on June 22, 1978 (43 Fed. Reg. 26962), and the comment period did not close until October 16, 1978 (43 Fed. Reg. 43331 (1978)), almost four months later. Three additional months elapsed before the final standard was promulgated on January 26, 1979. P.A. 43a.

The Review Group concluded that EPA's proposed ozone standard would result in little or no discernible benefit to public health, at the staggering cost of $14.3 to $18.8 billion *annually* (J.A. 661-62), or almost one percent of the Nation's gross national product. Accordingly, the Review Group suggested that an ozone standard of 0.16 ppm would still protect public health, while saving vast resources that society could use better to protect the public from other, far more serious, health hazards. J.A. 647-49, 665. [15] EPA rejected the Review Group's recommended standard of 0.16 ppm, without submitting its own proposal to the Science Advisory Board, and instead promulgated a far more stringent and costly standard of 0.12 ppm. [16] P.A. 43a.

In promulgating the standard, EPA rejected not only the requirement of independent scientific review, but also any meaningful substantive constraints on its standard-setting discretion. It refused to define what constitutes impairment of "public health" under § 109, or to acknowledge any limits on what "margin of safety" may be considered "adequate." P.A. 46a-48a. Similarly, EPA concluded that no other factors limit its discretion to determine what level of protection is "requisite to protect the public health," saying: "The Clean Air Act, as the

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[15] The Review Group found that "the marginal costs of EPA's proposed standard may be in the range of $1,100-$4,100 per reduced person-hour of ozone exposure, which causes discomfort but is reversible and apparently has no long-term debilitating effects." J.A. 637.

[16] The Review Group estimated that a standard of 0.12 ppm would cost $12.4 to $15 billion annually, which is almost $3 billion more *annually* than a standard of 0.16 ppm. J.A. 661.

Administrator interprets it, does not permit him to take factors such as cost[17] or attainability[18] into account in setting the standard." P.A. 82a.

The practical consequences of an ozone standard as stringent as that set by EPA are immense. The standard, which is violated in most parts of the country where ambient ozone is measured (P.A. 100a), must be attained by 1982, with an extension available only until 1987. 42 U.S.C. § 7502(a). Thus, states will be required to implement an array of control measures by next year to assure attainment by no later than 1987.[19] Even by

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[17] This view is rendered all the more inexplicable by EPA's recognition "that controlling ozone to very low levels is a task that will have significant impact on economic and social activities." P.A. 82a. EPA then stated that "[t]his recognition causes [the Administrator] to reject as an option the setting of a zero-level standard . . . However, it is public health, and not economic impact, that must be the compelling factor in the decision." *Id.*

No one disputes that public health is the "compelling factor" in setting a standard. But EPA never attempted to explain how practical factors could be irrelevant as a matter of law, while EPA may rely on those factors as the reason for avoiding a standard set at zero. Nor did EPA explain what factors bear on where the standard should be set, given the conceded fact that no standard provides absolute protection against all risks of health effects.

[18] During the rulemaking, EPA had funded private research which revealed that 80 percent of organic emissions come from vegetation rather than man-made sources. Because of the obvious significance of this information to the issue of whether the ozone standard could be attained by control of man-made emission sources, petitioners urged EPA during the comment period to consider the information in setting the standard. J.A. 1003. EPA refused to consider this evidence or to include it in the rulemaking record, claiming that whether a standard can be attained is irrelevant as a matter of law. J.A. 1071.

[19] States violating the ozone standard are subject to a variety of strict emission control requirements under section 110 (42 U.S.C. § 7410) and Part D (42 U.S.C. §§ 7501-08) of the Act. In addition, states unable to attain the primary ozone standard by 1982 must establish inspection and maintenance programs to control emissions from motor vehicles, among other measures. 42 U.S.C. § 7502(b)(11).

EPA's own estimates, ozone control measures required in 1982 and thereafter will cost billions of dollars annually. J.A. 659.[20]

C. The Decision Below

On petitions for review by industry groups and state and local governments, the court below upheld the standards in every respect.[21] The court ruled that EPA had violated § 8(e) of ERDDAA by failing to submit the proposed standards to the Science Advisory Board (P.A. 22a-23a), but excused the violation under § 307(d)(8) of the Act,[22] because "we cannot hold that the standard would likely have been significantly changed had it been submitted to the Board." P.A. 23a.[23] The court also endorsed EPA's construction of § 109, even though that construction places no effective limits on EPA's discretion, permitting EPA to set a standard of whatever stringency it chooses. P.A. 14a-15a.

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[20] EPA concedes that a number of states will be unable to attain the standard by the statutory deadlines, despite the implementation of all "reasonably available" control measures. When it promulgated the standard, EPA acknowledged that "[e]ven with aggressive control programs, however, it will be very difficult for some urban areas to achieve the standard within the next 10 years." P.A. 101a. Indeed, EPA already is establishing policies for states that will be unable to meet the final statutory deadline in 1987. 46 Fed. Reg. 7182 (1981). If EPA finds that, notwithstanding adoption of all reasonable measures, a state will not meet the standard, EPA may impose on the state a variety of more severe measures, including a ban on construction of major emission sources. 42 U.S.C. § 7410(a)(2)(I).

Once standards are established, neither technological nor economic infeasibility will relieve states or industrial sources from complying with these implementation requirements. Union Electric Co. v. EPA, 427 U.S. 246 (1976). One court upheld EPA regulations that could completely ban the sale of gasoline in Los Angeles if necessary to attain the ozone standard. City of Santa Rosa v. EPA, 534 F.2d 150 (9th Cir.), *cert. dismissed sub. nom.*, California v. EPA, 429 U.S. 952 (1976).

[21] The U.S. Court of Appeals for the District of Columbia Circuit is the sole forum for review of rules of nationwide scope under the Clean Air Act. 42 U.S.C. § 7607(b)(1), P.A. 107a. Accordingly, no conflict can develop among the circuits on some of the most important questions raised by the decision below.

[22] Section 307(d)(8) provides, in pertinent part: "In reviewing alleged procedural errors, the court may invalidate the rule only if the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed

REASONS FOR GRANTING THE WRIT

The decision below poses fundamental questions about whether Congress intended, or the Constitution permits, an administrative agency to exercise unchanneled and unreviewable discretion in making decisions of vast importance for public health and the economic well-being of the Nation. Unless reversed, the erroneous decision of the court of appeals will have far-reaching consequences for other cases by seriously undermining judicial review of administrative action.

There is a perplexing irony in the result reached below. Previous decisions of this Court and the court below have established a "highly deferential standard" of review for agencies' factual or policy determinations, especially those involving scientific or technical matters.[24] Judicial review in such

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if such errors had not been made." P.A. 111a. Although this requirement is incorporated by reference in § 307(d)(9)(D), P.A. 112a, the court below relied expressly on the provision of § 307(d)(8) in excusing EPA's statutory violations. P.A. 23a, 25a.

[23] The court declined to reach the issue of whether EPA violated the Federal Advisory Committee Act in privately convening its Advisory Panel, on the ground that such violations also would have been excusable. P.A. 25a. The court further down-graded the role of the Science Advisory Board by finding no reversible error in EPA's failure to respond to the Board's comments on the draft criteria document.

[24] *See, e.g.*, Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1145 (D.C. Cir.), *cert. denied*, 449 U.S. 1042 (1980) (*citing* Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971)), Industrial Union Dept., AFL-CIO v. Hodgson, 499 F.2d 467, 475 (D.C. Cir. 1974).

cases thus has focused on strict compliance with procedures required by law[25] or on issues of statutory interpretation and authority.[26] But the decision below, if allowed to stand, would close off even this limited scope of review by effectively immunizing EPA against claims of procedural irregularity in the development of standards,[27] and by confirming EPA's view that the statute gives it essentially unfettered discretion in setting those standards.

The court's reliance on § 307(d)(8) of the Clean Air Act not only absolves the Agency's flagrant violation of an express statutory requirement, but also defeats Congress' purpose in enacting § 8 of ERDDAA, which was to improve Agency decisionmaking and to enhance judicial review of EPA rules involving scientific issues. Only if ERDDAA is enforced can the independent scientific review process designed by Congress assist appellate courts in their review of Agency decisions on scientific and technical issues.[28]

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[25] Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 549, n.21 (1978) ("the court must determine whether the agency complied with the procedures mandated by the relevant statutes") (*citing* Citizens to Preserve Overton Park v. Volpe, 401 U.S. at 417); Ethyl Corp. v. EPA, 541 F.2d at 67 (concurring opinion of Judge Bazelon) ("we will do more to improve administrative decision-making by concentrating our efforts on strengthening administrative procedures").

[26] *See* Industrial Union Dept. v. American Petroleum Inst. 448 U.S. 607 (1980); American Tex. Mfg. Inst. v. Donovan, ____ U.S. ____, 101 S.Ct. 2478 (1981).

[27] In Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519 (1978), this Court admonished reviewing courts not to impose on administrative agencies procedures beyond those required by Congress. *Id.* at 546-49. The opinion below does just the opposite by announcing that courts need not enforce even procedural requirements, such as § 8 of ERDDAA, that Congress *expressly* provided.

[28] Judge Bazelon presaged the rationale for ERDDAA when he wrote: "[I]n cases of great technological complexity, the best way for courts to guard against unreasonable or erroneous administrative decisions is not for

This withdrawal of procedural checks exacerbates the grave constitutional questions posed by the court's interpretation of § 109 of the Clean Air Act. As interpreted by the court below, § 109 permits EPA to set a standard of whatever stringency it chooses. In contrast to OSHA's standard-setting authority recently construed by this Court in *Industrial Union Dept.* v. *American Petroleum Inst.*, 448 U.S. 607 (1980), EPA's standard-setting authority here is said not to be confined by any consideration of whether the risk to be prevented is significant (P.A. 15a), or even whether the standard can be attained by human effort. P.A. 14a-15a. Such a construction of § 109 thus would give EPA, even more than OSHA, "unprecedented power over American industry" and permit it to impose "enormous costs that might produce little, if any, discernible benefit." 448 U.S. at 645.

I. By Construing Section 307(d)(8) of the Clean Air Act to License Flagrant Violation of Mandatory Statutory Provisions, the Decision Below Raises Far-Reaching Questions About the Function and Scope of Judicial Review That Should Be Addressed by This Court.

The decision below presents a critical question about the nature and scope of judicial review under the Clean Air Act: may an appellate court, basing its decision on nothing but speculation, excuse as inconsequential error an agency's failure to comply with explicit and fundamental requirements laid down by Congress?

The court below answered this question in the affirmative, even though it agreed that ERDDAA "explicitly mandates that standards be submitted to the Board for review," and that

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the judges themselves to scrutinize the technical merits of each decision. Rather, it is to establish a decision-making process which assures a reasoned decision that can be held up to the scrutiny of the scientific community and the public." International Harvester Co. v. Ruckelshaus, 478 F.2d 615, 652 (D.C. Cir. 1973) (Bazelon, C.J., concurring).

"[a]ccordingly, the failure to submit the standards was a violation of procedure required by law." P.A. 22a-23a. Nevertheless, the court excused this express statutory violation as only an inconsequential "procedural" error under § 307(d)(8) of the Act, on the ground that EPA probably would have issued the same standard in any event. P.A. 23a.

The court's sweeping interpretation of § 307(d)(8), if allowed to stand, would eliminate effective judicial review of most, if not all, rulemaking requirements for Clean Air Act standards and regulations. Nothing could be of more "central relevance" to the establishment of an air quality standard than the advice of the Science Advisory Board as to whether the standard is supported by credible scientific evidence. When it enacted § 8 of ERDDAA, Congress decided that independent review of EPA's proposed standards was essential to ensure that final standards are based on adequate and reliable assessments of the scientific evidence.[29] By excusing EPA's flagrant violation of ERDDAA, the court's decision nullifies Congress' effort to ensure scientifically sound standards. Even more important, the court's opinion would preclude reversal of Clean Air Act rules for violation of virtually any rulemaking requirement. For if EPA may exclude the statutory Science Advisory Board from the standard-setting process, it may curtail public participation or otherwise tailor the rulemaking process to its convenience, based on no more than supposition that the final standard would not be substantially changed anyway.

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[29] Submission of the proposed standard to the Science Advisory Board was explicitly required by Congress *in addition to* submission of the draft criteria document. And for good reason, for it is at the proposal stage that EPA first draws factual conclusions and makes policy judgments that translate the underlying scientific information into a health standard affecting millions of people and vast amounts of society's resources. Although EPA is not required slavishly to follow the Board's advice, it is required to listen and to set forth the basis for its disagreement, if it disagrees. CAA § 307(d)(6)(B), P.A. 111a. *Cf.* CAA § 307(d)(3), P.A. 109a (requiring EPA to explain the reasons for any significant differences between EPA's proposal and the recommendations of the Scientific Review Committee established under § 109(d), P.A. 104a-105a).

In support of its holding, the court offered essentially no legal or factual analysis, reasoning simply that "[b]ecause any SAB review of the standard would have involved review of the criteria document, i.e., the scientific and technical basis for the standard, we cannot hold that the standard would likely have been significantly changed had it been submitted to the Board." P.A. 23a.[30] This conclusion rests on nothing but the court's view of its limited review function (P.A. 13a), and bare speculation about what effect Science Advisory Board review of the proposal might have had on the final standard.

The court implied that EPA's violation of ERDDAA was inconsequential because the record contained support for the rule as promulgated. P.A. 23a.[31] The difficulty with this rationale is that the record as a whole might not have provided adequate support for, or as a practical matter have allowed the Administrator to adopt, a final standard of 0.12 ppm if the

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[30] Remarkably, the court excused EPA's violation of ERDDAA by accepting the *same* EPA rationale that it had rejected in finding the violation in the first instance, *i.e.*, that the Board's review of the proposal, after having reviewed the draft criteria document, would have been redundant. P.A. 22a-23a. Under the court's broad reasoning, the Board's review of any proposed standard would be redundant.

[31] The court's rationale is tantamount to requiring that the standard be unsupportable by the record before it can be reversed on procedural grounds. This approach effectively collapses the basis for procedural reversal into the "arbitrary and capricious" standard for substantive review, even though § 307(d)(9)(D) establishes a separate and independent basis for reversal where a procedural error might have affected the final standard. P.A. 112a. Under § 307(d)(8), the question is not whether the standard is supported by the existing incomplete record, but rather whether the Administrator might have reached a different result if he had followed the standard-setting process prescribed by Congress.

Board had been allowed to comment on the proposed rule.[32] Even the most dedicated proponent of EPA's final standard could not readily have defended that result if both the Regulatory Analysis Review Group (*supra* at 8) and the Science Advisory Board had supported a higher standard.[33]

The legislative history of § 307(d)(8) shows that it was never intended to curtail judicial review or to sanction the blanket immunity from statutory violations granted by the court below. Thus, the House Committee where § 307(d) originated emphasized that "in the committee's view, appropriately broad administrative discretion to promulgate regulations to protect health or the environment *must be restrained by thorough and careful procedural safeguards*. . . ."[34] Later, the Conference Committee reiterated that "the conferees intend that the courts continue their *thorough, comprehensive review* which has characterized judicial proceedings under the Clean Air Act thus far."[35]

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[32] There is, of course, every reason to believe that the Board would have advocated a higher standard than the one actually adopted. Chairman Whittenberger concluded that the health sections of the draft criteria document were "speculative, incomplete, and heavily dependent on studies of questionable validity." J.A. 293. Another member, Dr. McCarroll, emphasized that "[w]hat comes through loud and clear in most of these chapters to me is the fact that there is no demonstrable health effect before .25 ppm, either human or animal exposure." J.A. Ex. 2 at 507.

[33] The court made its prediction under § 307(d)(8) without the benefit of any showing by EPA that the Board's review would have been irrelevant. In remanding a case based on agency error, the late Judge Leventhal concluded that "whether the agency would have reached the same result if it had not made these erroneous findings . . . is the type of issue on which we think it is appropriate to insist on further guidance from the agency." Braniff Airways, Inc. v. CAB, 379 F.2d 453, 467 (D.C. Cir. 1967).

[34] H.R. Rep. No. 294, 95th Cong., 1st Sess., *reprinted in* [1977] U.S. Code Cong. & Ad. News 1077, 1398 (emphasis is added throughout this Petition unless otherwise noted).

[35] H.R. Rep. No. 564, 95th Cong., 1st Sess., *reprinted in* [1977] U.S. Code Cong. & Ad. News 1502, 1559.

Indeed, it is questionable whether § 307(d)(8) has any application at all to EPA's violation of ERDDAA. By its own terms, § 307(d)(8) applies only to "procedural determinations made by the Administrator *under this subsection*," P.A. 111a,[36] and not to violations of entirely different statutes such as ERDDAA.[37] Moreover, § 8 of ERDDAA is more fairly characterized as a mandatory prerequisite to EPA's exercise of its standard-setting authority, *i.e.*, a "statutory limitation" within the meaning of § 307(d)(9)(C), P.A. 112a,[38] rather than a "procedural" requirement subject to §§ 307(d)(8) and (d)(9)(D).[39]

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[36] The Committee Report for H.R. 6161, where § 307(d) originated, shows that § 307(d)(8) was included to underscore the Administrator's discretion to grant cross-examination under § 307(d) based on the circumstances of each case. H.R. Rep. No. 294, 95th Cong., 1st Sess., *reprinted in* [1977] U.S. Code Cong. & Ad. News 1401, 1399-1400. The Conference Committee deleted the discretionary provision for cross-examination, but without explanation neglected to delete the companion provision of § 307(d)(8). H.R. Rep. No. 564, 95th Cong., 1st Sess., *reprinted in* [1977] U.S. Code Cong. & Ad. News 1557-59.

[37] Congress enacted ERDDAA several months *after* § 307(d)(8) became law, without any suggestion that violations of ERDDAA should be excused under § 307(d)(8).

[38] Section 307(d)(9)(C) of the Act requires reversal whenever EPA's action is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." P.A. 112a.

[39] Science Advisory Board review should be treated as just such a "statutory limitation" on EPA's authority. Unlike most "procedural" rules, the requirement for Science Advisory Board review concerns not access by interested parties to the decision-making process, but rather access by the decisionmaker to the views of the especially qualified, disinterested reviewers comprising the Science Advisory Board.

See also provisions of the National Environmental Policy Act, 42 U.S.C. § 4332(2)(C) (which have been treated as mandatory adjuncts to an agency's exercise of its authority; Kleppe v. Sierra Club, 427 U.S. 390, 409 (1976), Flint Ridge Dev. Co. v. Scenic Rivers Ass'n, 426 U.S. 776, 787 (1976), Accordingly, because the court below erroneously construed § 307(d)(8) in a manner that not only will excuse violations of a critical standard-setting reform provision, but also severely curtail judicial review of future Clean Air Act rulemakings, this is a compelling case for the exercise of this Court's discretionary jurisdiction.

II. The Decision Below Raises Grave Constitutional Questions By Construing Section 109 of the Clean Air Act as Placing No Limitations on EPA's Standard-Setting Discretion.

The decision below removes all effective constraints on EPA's discretion, permitting it to set national ambient air quality standards of whatever stringency it chooses. Given the court's expansive interpretation of § 307(d)(8) to permit departures from the rulemaking process, it becomes all the more critical that there be discernible substantive limits on EPA's standard-setting authority. But the court below found none.

EPA's authority to promulgate primary air quality standards derives entirely from § 109 of the Act, which describes those standards simply as "standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." P.A. 104a. The conceded purpose of such standards thus is to "protect the public health." Nowhere, however, does the Act specify exactly what degree of protection Congress meant to provide when it used terms such as "adequate margin of safety," or "requisite to protect the public health." Obviously EPA must choose a specific level of protection when it sets a standard. But as interpreted by EPA, § 109 would merely exhort EPA to pursue a worthy objective, while excluding consideration of any factors bearing on how far to go in pursuit of that goal.

Calvert Cliffs' Coordinating Comm. v. U.S. Atomic Energy Comm'n, 449 F.2d 1109, 1114-15 (D.C. Cir. 1971), Duck River Preservation Ass'n v. TVA, 410 F. Supp. 758, 766-67 (E.D. Tenn. 1974), *aff'd mem.*, 529 F.2d 524 (6th Cir. 1976)).

Neither EPA nor the court below defined key terms in § 109 in such a way as to place any constraints on EPA's discretion to set a standard of whatever stringency it chooses. Rather than confining its standard-setting mandate within bounds capable of review by the courts, EPA simply recited the statutory text, and emphasized the paramount role of its "judgment" in identifying the desirable level of public health protection.[40] EPA conceded that unspecified economic and social considerations would preclude setting a zero-level standard to avoid all health risks, but nowhere did EPA or the court even attempt to limit the Agency's judgment to protecting against significant risks to public health. Moreover, both expressly rejected other factors that could provide a check on EPA's discretion, by precluding consideration of all practical matters, including whether the standard could be attained through human effort. P.A. 14a-15a.

This extreme construction of § 109 would grant EPA such unchecked discretion as to render the provision an unconstitutional delegation of legislative authority. Congress may not simply leave legislative decisions with enormous consequences, such as setting the ozone standard, to the unconfined "judgment" of an administrative officer. Rather, the decisions of this Court require that Congress set out an "intelligible principle" to guide administrative decisions, and to serve as a standard against which the administrative decision may be reviewed by the courts. *Hampton & Co.* v. *United States,* 276 U.S. 394, 409 (1928), *Panama Refining Co.* v. *Ryan,* 293 U.S. 388, 430 (1935), *Industrial Union Dept.* v. *American Petroleum Institute,* 448 U.S. 607, 685-87 (1980) (concurring opinion of Justice Rehnquist).

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[40] EPA explained the statutory provision for an "adequate margin of safety" by saying simply that "EPA feels that the decision regarding an adequate margin of safety is a *judgment* which must be made by the Administrator after weighing *all* the medical evidence bearing on ozone." (emphasis in original). P.A. 70a. EPA offered no more limited construction of the term.

The severe problems posed by sweeping delegations of legislative authority are vividly illustrated by this Court's recent decision in *Industrial Union Dept.* v. *American Petroleum Institute* (the *Benzene* case), 448 U.S. 607 (1980), which interpreted analogous provisions of the Occupational Safety and Health (OSH) Act, 29 U.S.C. § 651 *et seq.*, to avoid an unconstitutional delegation. The OSH Act gives OSHA broad discretion to issue health and safety standards, but requires that those standards be "feasible" (§ 6(b)(5), 29 U.S.C. § 655(b)(5)), as well as "reasonably necessary or appropriate to provide safe or healthful employment" (§ 3(8), 29 U.S.C. § 652(8)). OSHA claimed that these provisions required it to set standards at the lowest technologically feasible level that would not impair the viability of the industries regulated. 448 U.S. at 639. The Court rejected OSHA's contention, and construed § 3(8) as requiring OSHA to make a threshold finding of "significant risk" before issuing a standard. 448 U.S. at 642. Justice Stevens reasoned that, unless § 3(8) were so construed, "the statute would make such a 'sweeping delegation of legislative power' that it might be unconstitutional" under the Court's prior decisions. *Id.* at 646.

The Clean Air Act as construed by EPA and the court below would present an even more grievous delegation problem than did the OSH Act. Even before this Court's *Benzene* decision, OSHA's discretion was conceded to be constrained by the requirement that standards protect only against "material impairment" of health, and that standards be technologically and economically "feasible." 29 U.S.C. § 655(b)(5). By contrast, the court below construed § 109 of the Clean Air Act not only to dispense with any requirement of material health impairment or significant risk (P.A. 15a-16a), but also to preclude any consideration of feasibility. P.A. 14a-15a.

The constitutional deficiency resulting from the lower court's interpretation of § 109 is compounded by its construction of § 307(d)(8), which would preclude judicial enforcement of even the most fundamental procedural requirements.[41] Here, the court of appeals essentially nullified applicable procedural requirements, even while affirming a sweeping grant of substantive authority to the Agency. By so doing, the court has left no effective judicial checks, either substantive or procedural, on EPA's discretion.

The standard-setting provisions of § 109 can be upheld as constitutional if properly construed to impose effective limitations on EPA's authority.[42] Although the decision below gives EPA no meaningful guidance on the degree of protection to provide for public health, the statutory text of § 109(b)(1) can be and should have been construed to place reasonable constraints on EPA's standard-setting authority.

By describing primary standards in § 109(b)(1) as those "*requisite to protect* the public health," Congress indicated that standards should be no more stringent than necessary to provide protection against significant risks to health. Therefore, like the OSH Act requirement that standards be "*reasonably necessary* or appropriate to provide *safe* or *healthful* employment," § 109(b)(1) should have been construed to require EPA to make a threshold finding of significant risk before setting the standard.[43]

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[41] The presence of mandatory administrative procedures may be important in upholding broad substantive grants of authority from constitutional infirmity. Lichter v. United States, 334 U.S. 742, 786-87 (1948). *See also* Schechter Corp. v. United States, 295 U.S. 495, 553 (1935), where the Court found the statutory provision to be unconstitutional because, in part, it lacked the procedural requirements found in other regulatory statutes; Panama Refining Co. v. Ryan, 293 U.S. at 432.

[42] Grants of administrative authority should be reasonably construed whenever possible to avoid having to reach the constitutional question posed by the nondelegation doctrine. Industrial Union Dept. v. American Petroleum Institute, 448 U.S. 607, 646 (1980), National Cable Television Ass'n v. United States, 415 U.S. 336, 341-43 (1974).

The legislative history supports such a requirement of significant risk for ambient air quality standards. Thus, the Senate Committee in which § 109 originated said that primary standards should provide a "*reasonable* degree of protection . . . against hazards which research has not yet identified . . . ."[44] The decision below goes far beyond these limitations to permit EPA to set standards at any point on the continuum of risk.

Nor did Congress intend for EPA, while protecting the public health, to blind itself to practical considerations such as whether a standard can be attained at all, or whether an additional increment of protection is "reasonable" in light of what society must sacrifice to achieve it. The entire structure of the Act contemplates the attainment of standards. In the absence of an express provision to the contrary, § 109(b)(1) should be construed to require the Administrator to consider both expected health benefits and attainment costs in deciding what standard provides an "adequate margin of safety." This result comports with a common-sense reading of the statute.[45]

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[43] In the Court's *Benzene* decision, Justice Stevens said that " 'safe' [and presumably 'healthful' as well] is not the equivalent of 'risk-free.' There are many activities that we engage in every day—such as driving a car *or even breathing city air* — that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.' " 448 U.S. at 642.

[44] S. Rep. No. 1196, 91st Cong., 2d Sess. 10 (1970).

[45] Any other interpretation would waste society's scarce resources, and thereby diminish society's ability to protect public health or to achieve other important objectives. Justice Stevens made a similar point in the *Benzene* case when he concluded that "[i]n the absence of a clear mandate in the Act, it is unreasonable to assume that Congress intended to give the Secretary the unprecedented power over American industry that would result from the Government's view. . . . [T]he Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit." 448 U.S. at 645.

Indeed, EPA itself is unable to interpret § 109 in a manner that excludes practical considerations altogether.[46] Thus EPA concedes that without some consideration of practical factors in determining what level of protection is "adequate," there would be no reason to accept less than the absolute safety of a zero standard. P.A. 82a. But given its own concession that such factors preclude a zero-level standard, EPA cannot argue that the statute bars consideration of the same factors in determining whether a "margin of safety" is "adequate" for standards set at a level above zero. Rather, EPA's inconsistency can only be interpreted as an attempt to maintain unfettered discretion to consider practical factors whenever it wants, without being held accountable on judicial review.

In short, § 109 of the Clean Air Act should be construed as placing reasonable limits on EPA's standard-setting discretion. Otherwise, § 109 must be invalidated as an unconstitutional delegation because Congress failed to make the "hard choices" on "quintessential" legislative issues of great importance. 448 U.S. at 686 (concurring opinion of Justice Rehnquist).

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[46] Practical factors should be considered also because EPA construes the related provisions of § 112 of the Clean Air Act, P.A. 105a, to permit consideration of such factors in setting emission standards for "hazardous" air pollutants. 44 Fed. Reg. 58642, 58661 (1979). Section 112 differs from § 109 in that § 112 governs the class of more serious "hazardous" pollutants, and therefore requires an "ample" rather than just an "adequate" margin of safety. Yet in construing the phrase "ample margin of safety" in § 112, EPA has said that "there is no reason to believe that Congress intended to make air pollution practically the sole facet of American life from which the government would attempt to eliminate risk entirely." *Id.* Accordingly, EPA considered economic and technological factors in promulgating standards under § 112 for both asbestos and vinyl chloride. *See* 38 Fed. Reg. 8820 (1973) (asbestos); 40 Fed. Reg. 59532 (1975), 41 Fed. Reg. 46560 (1976), 42 Fed. Reg. 28154 (1977) (vinyl chloride).

CONCLUSION

For the foregoing reasons, the Court should grant this Petition for Certiorari.

Respectfully submitted,

Edward W. Warren*
Robert F. VanVoorhees
John S. Hahn
Kirkland & Ellis
1776 K Street, N.W.
Washington, D.C. 20006
(202) 857-5000

Counsel for American Petroleum Institute and Member Company Petitioners

John H. Pickering
William H. Lewis, Jr.
David R. Johnson
Wilmer, Cutler & Pickering
1666 K Street, N.W.
Washington, D.C. 20006

Counsel for Chemical Manufacturers Association

J. Marshall Coleman
Attorney General of Virginia
Roger L. Chaffe
Assistant Attorney General
Suite 308
11 South 12th Street
Richmond, Virginia 23219

Counsel for the Commonwealth of Virginia, ex rel. the State Air Pollution Control Board

Bernard J. Reilly
1007 Market Street
Wilmington, Delaware 19898

Counsel for E. I. du Pont de Nemours & Company

Of Counsel:
Stark Ritchie
David T. Deal
American Petroleum Institute

Edmund B. Frost
Chemical Manufacturers Association

November 10, 1981

**Counsel of Record*

Wilkes C. Robinson
J. Scott Brown
Gulf Coast & Great Plains
Legal Foundation
127 West 10th Street
Room 1022
Kansas City, Missouri 64105
Counsel for St. Louis Regional Commerce and Growth Association

Jan Eric Cartwright
Attorney General of Oklahoma
Neal Leader
Assistant Attorney General
112 State Capitol Building
Oklahoma City, Oklahoma 73105
Counsel for State of Oklahoma

Appendix

I

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No. 81-871

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Petitioners,

v.

ANNE M. GORSUCH, ADMINISTRATOR,
AND ENVIRONMENTAL PROTECTION AGENCY,
Respondents.

APPENDIX TO JOINT PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Of Counsel:
STARK RITCHIE
DAVID T. DEAL
American Petroleum Institute
EDMUND B. FROST
Chemical Manufacturers Association

November 10, 1981

EDWARD W. WARREN*
ROBERT F. VANVOORHEES
JOHN S. HAHN
KIRKLAND & ELLIS
1776 K Street, N.W.
Washington, D.C. 20006
(202) 857-5000
Counsel for American Petroleum Institute and Member Company Petitioners

JOHN H. PICKERING
WILLIAM H. LEWIS, JR.
DAVID R. JOHNSON
WILMER, CUTLER & PICKERING
1666 K Street, N.W.
Washington, D.C. 20006
Counsel for Chemical Manufacturers Association

**Counsel of Record*

Additional counsel listed inside cover.

PRESS OF BYRON S. ADAMS PRINTING, INC., WASHINGTON, D.C.

J. MARSHALL COLEMAN
ATTORNEY GENERAL OF VIRGINIA
ROGER L. CHAFFE
ASSISTANT ATTORNEY GENERAL
Suite 308
11 South 12th Street
Richmond, Virginia 23219

Counsel for the Commonwealth of Virginia, ex rel. the State Air Pollution Control Board

BERNARD J. REILLY
1007 Market Street
Wilmington, Delaware 19898

Counsel for E. I. du Pont de Nemours & Company

WILKES C. ROBINSON
J. SCOTT BROWN
GULF COAST & GREAT PLAINS
LEGAL FOUNDATION
127 West 10th Street
Room 1022
Kansas City, Missouri 64105

Counsel for St. Louis Regional Commerce and Growth Association

JAN ERIC CARTWRIGHT
ATTORNEY GENERAL OF OKLAHOMA
NEAL LEADER
ASSISTANT ATTORNEY GENERAL
112 State Capitol Building
Oklahoma City, Oklahoma 73105

Counsel for State of Oklahoma

APPENDIX A

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 79-1104

AMERICAN PETROLEUM INSTITUTE, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, and
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

AMERICAN PETROLEUM INSTITUTE AND 15
OF ITS MEMBER COMPANIES,
CHEMICAL MANUFACTURERS ASSOCIATION,
THE ST. LOUIS REGIONAL COMMERCE &
GROWTH ASSOCIATION,
NATURAL RESOURCES DEFENSE COUNCIL, ET AL.,
THE STATE OF OKLAHOMA,
E.I. DU PONT DE NEMOURS & CO., INTERVENORS

No. 79-1201

E.I. DU PONT DE NEMOURS AND COMPANY, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, and
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

No. 79-1222

AMERICAN PETROLEUM INSTITUTE, ET AL., PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY, and
DOUGLAS M. COSTLE, ADMINISTRATOR

No. 79-1290

CHEMICAL MANUFACTURERS ASSOCIATION, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, and
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1335

THE NATURAL RESOURCES DEFENSE COUNCIL, INC.,
ET AL., PETITIONERS

v.

DOUGLAS M. COSTLE, ADMINISTRATOR OF THE
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1359

CHEMICAL MANUFACTURERS ASSOCIATION, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, and
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1362

THE CONNECTICUT LUNG ASSOCIATION, INC., PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR OF THE
U.S. ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1356

SIERRA CLUB, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR OF THE
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1365

COMMONWEALTH OF VIRGINIA, *ex rel.*
THE STATE AIR POLLUTION CONTROL BOARD, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY and
DOUGLAS M. COSTLE, ADMINISTRATOR, RESPONDENT

No. 79-1367

CITY OF HOUSTON, TEXAS, PETITIONER

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
and DOUGLAS M. COSTLE, ADMINISTRATOR, RESPONDENT

Petitions for Review of Orders of the
Environmental Protection Agency

Argued February 26, 1980

Decided September 3, 1981

Edward W. Warren with whom *Robert F. Van Voorhees, John S. Hahn, Stark Ritchie* and *David T. Deal* were on the brief, for American Petroleum Institute petitioner in Nos. 79-1104 and 79-1222 and intervenor in Nos. 79-1335, 79-1356 and 79-1362.

Roger L. Chaffe, Assistant Attorney General, for Commonwealth of Virginia, etc., petitioner in No. 79-1365. *Frederick S. Fisher* and *James E. Ryan, Jr.,* also entered appearances for Commonwealth of Virginia, etc., petitioner in No. 79-1365.

Courtenay Ellis with whom *David A. Donohoe* was on the brief, for City of Houston, Texas, petitioner in No. 79-1367. *Daniel Joseph* also entered an appearance for City of Houston, Texas, petitioner in No. 79-1367.

Richard Ayres with whom *David D. Doniger* was on the brief, for Natural Resources Defense Council, Inc., et al., petitioner in Nos. 79-1335, and 79-1362 and intervenor in No. 79-1104.

John H. Pickering, Andrew T. A. MacDonald and *Edmund B. Frost* were on the brief, for Chemical Manufacturers Association petitioner in Nos. 79-1290 and 79-1359 and Intervenor in Nos. 79-1104, 79-1335, 79-1356 and 79-1362. *David R. Johnson* and *John Stephen Lawrence, Jr.,* also entered appearances for Chemical Manufacturers Association, petitioner in Nos. 79-1290 and 79-1359 and intervenors in Nos. 79-1335, 79-1356 and 79-1362.

Joseph J. Brecher was on the brief, for Sierra Club, Petitioner in No. 79-1356. *Peter J. Herzberg* also entered an appearance for Sierra Club, petitioner in No. 79-1356.

Patrick K. O'Hare, Attorney, Environmental Protection Agency and *Patrick J. Cafferty, Jr.*, Attorney, Department of Justice with whom *Angus Macbeth*, Acting Assistant Attorney General, *Donald W. Stever*, Attorney, Department of Justice and *Gerald K. Gleason*, Deputy Associate General Counsel, Environmental Protection Agency were on the brief, for respondents. *Jeffrey O. Cerar*, Attorney, Environmental Protection Agency also entered an appearance for respondent, Environmental Protection Agency.

Christopher S. Bond and *Charles A. Blackman* were on the brief, for the St. Louis Regional Commerce and Growth Association, intervenor in Nos. 79-1104, 79-1335, 79-1356 and 79-1362.

Charles S. Rogers, Assistant Attorney General, State of Oklahoma also entered an appearance for State of Oklahoma, etc., intervenor in No. 79-1104.

Robert R. Bonczek, *Carl B. Everett*, and *Bernard J. Reilly* also entered appearances for E.I. DuPont De Nemours and Company petitioner in No. 79-1201 and intervenor in Nos. 79-1104, 79-1335, 79-1356 and 79-1362.

Before: ROBB, WALD and MIKVA, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* ROBB.

Opinion dissenting in part filed by *Circuit Judge* WALD.

ROBB, *Circuit Judge*: The petitions for review consolidated in this case challenge the primary and secondary national ambient air quality standards[1] for ozone promulgated by the Environmental Protection Agency (EPA) under the Clean Air Act, as amended. 42 U.S.C. §§ 7401, *et seq.* (Supp. III 1979). EPA established both the primary and secondary standards for ozone at 0.12

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[1] These regulations are codified at 40 C.F.R. § 50.9(a) (1980).

parts per million (ppm) in final regulations published on February 8, 1979. 44 Fed. Reg. 8202. Petitioners American Petroleum Institute (API), *et al.*, the City of Houston, and the Commonwealth of Virginia contend that the Administrator of EPA erred by establishing too stringent standards. Petitioner National Resources Defense Council (NRDC), *et al.*, argues that the Administrator erred by establishing standards that are too lenient. Various petitioners raise procedural challenges, and certain petitioners challenge regulations which implement the standards. We uphold the ozone standards because they are proper under the Act and such procedural errors as did occur do not require invalidation of the final standards.

I.

The standards challenged in this case establish restrictions on permissible levels of ozone. As with other photochemical oxidants, ozone is not emitted directly into the air, but is produced by complex chemical reactions between organic compounds (precursors) and nitrogen oxides in the presence of sunlight. Oxidant precursors are organic compounds which can occur naturally but are in large measure man-made. Sources of precursors include automobile emissions of hydrocarbons, chemical plant emissions, and gasoline vapors. Photochemical oxidant concentrations can also exist where ozone from the stratosphere intrudes into the lower atmosphere or where naturally occurring nitrogen oxides react with hydrocarbons produced by vegetation. Although ozone is but one of many photochemical oxidants, total oxidant pollution has been measured by reference to the ozone level in the air since 1971.

Ozone is the primary cause of the ill effects associated with smog, of which it usually comprises 65-100%. At certain concentration levels, ozone irritates the respiratory system and causes coughing, wheezing, chest tightness, and headaches. Due to its irritating nature, ozone can aggravate asthma, bronchitis, and emphysema. Some studies indicate that chronic exposure to fairly low levels of ozone may reduce resistance to infection and alter blood chemistry or chromosone structure. Ozone can destroy vegetation, reduce crop yield, and damage exposed materials by causing cracking, fading, and weathering.

The goal of the Clean Air Act is to protect the public health and welfare by improving the quality of the nation's air. 42 U.S.C. § 7401(b). Improved air quality is accomplished by the establishment of national ambient air quality standards (NAAQS) and by implementation thereof through state programs to control local sources of pollution. 42 U.S.C. § 7410. The Act directs the Administrator to establish two types of NAAQS. Primary ambient air quality standards are "standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." 42 U.S.C. § 7409(b)(1). Secondary standards "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." 42 U.S.C. § 7409(b)(2). State control programs must provide for the attainment of primary standards "as expeditiously as practicable but . . . in no case later than three years from the date of aproval of such plan . . ." 42 U.S.C § 7410(a)(2)(A)(i). State programs that implement secondary standards must specify a "reasonable time at which such secondary standard will be attained". 42 U.S.C. § 7410(a)(2)(A)(ii). Thus, the ozone standards at issue in this case must be implemented through state plans within three years for the primary standard and within a reasonable time for the secondary standards.[2] *Lead Industries Ass'n v. EPA*, No. 78-2201 (D.C. Cir. June 27, 1980) slip op. at 7-8, *cert. denied*, 49 U.S.L.W. 3428 (Dec. 8, 1980).

EPA promulgated primary and secondary standards for photochemical oxidants (i.e., ozone) in 1971. Both standards were established at an 0.08 ppm hourly average not to be exceeded more than once a year. 36 Fed. Reg. 8187 (1971). The method used to determine compliance with the 1971 standards measured only ozone. 43 Fed. Reg. 26967 (1978). In 1976 EPA began to revise the 1971 standards and in April 1977 requested data and information relevant to the revision. 42 Fed. Reg. 20493 (1977).

As part of the revision, EPA established a working group within the Criteria and Special Studies Office of its Office of Research and Development to develop a "criteria document". A criteria document "accurately reflect[s] the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." 42 U.S.C. § 7408(a)(2); *see* 42 U.S.C. § 7409(a). In the early stages of preparing the ozone criteria document EPA retained a panel of expert environmental consultants (the Shy Panel) and sought their opinions on the ozone concentration levels at which adverse health effects might be experienced. The Shy Panel concluded that "short term exposures to ozone in the range of 0.15 to 0.25 ppm may impair mechanical function of the lung, and may induce respiratory and

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[2] Under 42 U.S.C. § 7501(a)(2) a state that cannot meet the NAAQS for ozone by December 31, 1982 despite the implementation of "all reasonably available measures" may seek approval of a plan that extends the deadline for compliance to December 31, 1987.

related symptoms in sensitive segments of the population". (J.A. 270) The panel recommended that the primary standard remain at 0.08 ppm. (J.A. 277) The panel's recommendations and conclusions were included in the draft criteria document.

In 1974 the Administrator of the EPA established a Science Advisory Board (SAB) to assist in establishing NAAQS, among other functions. During the revision of the ozone standards Congress passed the Environmental Research, Development, and Demonstration Authorization Act of 1978, PUB.L. 95-155, 91 Stat. 1260 (1978) (ERDDAA), which requires the Administrator to submit to the SAB any "proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the [EPA] . . . on which the proposed action is based." 42 U.S.C. § 4365(e). During the revision of the ozone standard the SAB reviewed two full drafts and a third draft of the summary chapter of the ozone criteria document and offered comments on its content. After examining the summary of the third draft, six of the eleven SAB members voted to approve the criteria document, with reservations and recommended changes. Two members rejected the document, and three members offered no judgment. The parties dispute the effect of this "approval" under the Clean Air Act. Neither the final criteria document nor the final ozone standards were made available to the SAB for comment.

As a further aid to the Administrator in establishing the ozone standards, EPA conducted a "risk assessment study". This study combined medical opinions as to the necessary ozone levels for creation of certain adverse health effects (e.g., aggravation of emphysema) with predictions as to peak ozone levels in a five-year period. (J.A. 561-73) The study attempted to predict the probability of creating certain health problems under various possible standards. The Shy Panel relied on the results of this study in recommending that the primary standard remain at 0.08 ppm. Although the risk assessment study results were summarized in the preamble to the final regulations, 44 Fed. Reg. 8216 (1979), the Administrator acknowledged that the method used in arriving at the results was not completely reliable. 44 Fed. Reg. 8210-11 (1979). The parties dispute whether the results of the risk assessment study played a significant role in the establishment of the ozone standards.

On June 22, 1978 EPA published the proposed primary and secondary standards for ozone. 43 Fed. Reg. 26962. The proposed primary standard was raised to 0.10 ppm, while the proposed secondary standard remained at 0.08 ppm. EPA also proposed a revision in the measuring standard (the one-exceedance-per-year attainment measure) by substitution of a new standard. Under the old standard, as long as the 0.08 ppm standard was not exceeded more than once a year, the standard was met. The new measuring standard is met when "the expected number of hour[s] per calendar year with concentrations above 0.10 ppm is less than or equal to one [over a three year period]". 43 Fed. Reg. 26968 (1978). In setting the proposed primary standard at 0.10 ppm the Administrator relied on studies showing adverse health effects at ozone concentrations of 0.15 to 0.35 ppm. 43 Fed. Reg. 26966 (1978). He also relied on medical opinions and some of the conclusions of the risk assessment study. *Id.* at 26966-67. The proposed secondary standard was based on predictions as to the effects of certain ozone concentrations on crop yields due to leaf damage. 43 Fed. Reg. 26969 (1978).

After publication of the proposed standards, EPA conducted four public hearings on the standards and received numerous comments. Various governmental agencies commented on the proposed standards, including the

Departments of Interior, Energy, and Transportation, the United States Public Health Service, the Virginia Air Pollution Control Board, and various White House officials. 44 Fed. Reg. 8206-07 (1979). Some of these comments occurred after the official comment period closed and are the subject of dispute in this case.

In February 1979 EPA published final primary and secondary standards for ozone, raising both to 0.12 ppm. 44 Fed. Reg. 8202. The Administrator determined that "the most probable level for adverse health effects in sensitive persons, as well as in healthier (less sensitive) persons who are exercising vigorously, falls in the range of 0.15 to 0.25 ppm." 44 Fed. Reg. 8216 (1979). He based his conclusion on the criteria document, the comments submitted on the proposed standards, the report of the Shy Panel, and medical opinions collected during the risk assessment study. 44 Fed. Reg. 8215-16 (1979). The Administrator also concluded that the 0.12 ppm standard provides an adequate margin of safety. 44 Fed. Reg. 8216-17 (1979). He raised the proposed secondary standard based on a determination that average daily maximum ozone concentrations of 0.12 ppm would not harm crop yields. 44 Fed. Reg. 8217-18 (1979). Finally, in addition to establishing ozone standards, EPA published four models for determining the amount of hydrocarbon reduction necessary to meet the standards. 44 Fed. Reg. 8234 (1979). No petitions for reconsideration of the standards were filed with EPA. Petitions for review pursuant to 42 U.S.C. § 7607(b)(1) followed.

II.

ISSUES PRESENTED BY THE PETITIONS

The petitions for review present both substantive and procedural challenges to the primary and secondary ozone standards promulgated by EPA. Some petitioners contend that the standards are irrational and unsupported by the record. Other petitioners argue that the standards do not contain an adequate margin of safety, are too stringent given naturally occurring ozone levels, and are not economically feasible. It is also argued that the measurement standards and control strategies promulgated by EPA are unreasonable and unsupported by the record. As to the procedural allegations, it is argued that the Administrator erred in his use of the Science Advisory Board, the Shy Panel, and the risk assessment study. Various petitioners contend that certain items excluded from the record should have been included, while other petitioners argue that some material was untimely inserted in the record. After discussing the standard of review which governs petitions for review under the Clean Air Act, we address each significant argument in turn.

III.

STANDARD OF REVIEW

Section 307 of the Clean Air Act provides, in relevant part:

* * * *

> (b) (1) A petition for review of action of the Administrator in promulgating any national primary or secondary ambient air quality standard . . . may be filed only in the United States Court of Appeals for the District of Columbia.
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> * * * *
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> (d) (1) This subsection applies to—
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> (A) the promulgation or revision of any national ambient air quality standard under section 7409 of this title.
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> * * * *
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> (9) In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action found to be—

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
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> (B) contrary to constitutional right, power, privilege or immunity;
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> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or
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> (D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary or capricious, (ii) the requirement of . . . [a timely objection] has been met, and (iii) [the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made] . . . .

* * * *

42 U.S.C. § 7607.

These provisions of the Act assign this court a restricted role in reviewing air quality standards. *Lead Industries Ass'n, Inc. v. EPA, supra* at 30. The Administrator's construction of the Act will be upheld if it is reasonable, *id.* at 29-30, and though it is our duty to undertake a "searching and careful" inquiry into the facts, our view of the evidence "is not designed to enable us to second-guess the agency's expert decisionmaker." *Id.* at 26, 27. Reversal for procedural defaults under the Act will be rare because the court must first find that the Administrator was arbitrary or capricious, that he overruled a relevant and timely objection on the point in question, and that the errors were so significant that the challenged rule would likely have been different without the error. 42 U.S.C. § 7607(d)(9)(D); *Sierra Club v. Costle*, No. 79-1565 (D.C. Cir. April 29, 1981) slip op. at 182-83, 193-94.

IV.

SUBSTANTIVE CHALLANGES TO THE OZONE STANDARDS

Petitioner American Petroleum Institute contends that the primary ozone standard is not rational because, it alleges, no adverse health effects have been proven below 0.25 ppm with two hours exposure. (Br. for API at 31-44) API also argues that EPA must consider whether the 0.12 ppm standard is attainable and whether the anticipated costs of meeting that standard are justified when compared with the results to be achieved. *Id.* at 51-68. Petitioner Houston contends that the ozone standards are arbitrary and capricious because natural ozone levels and other physical phenomena in the Houston area prevent it from meeting the standards. (Br. for Houston at 4-22) Houston argues that the standards are also arbitrary and capricious because the control strategies promulgated by EPA will not reduce ozone levels. *Id.* at 22-26.

Petitioner Commonwealth of Virginia contends that EPA acted arbitrarily and capriciously in retaining the single hour averaging test for measuring compliance with the ozone standards. Virginia argues that the method chosen is not supported by logic or medical evidence, is costly, and will have no demonstrable beneficial effect on air quality. (Br. for Virginia at 3-13) Petitioner Natural Resources Defense Council contends that the Administrator misinterpreted the Act in adopting standards for ozone alone and thus rescinding existing standards for other photochemical oxidants. (Br. for NRDC at 35-44) NRDC also argues that the Administrator failed to establish an adequate margin of safety in the primary ozone standard. *Id.* at 44-66.

API's argument that the Administrator erred in not considering attainability and cost justifications for the ozone standards was specifically rejected in the *Lead Industries* case, *supra* at 32. We stated there that under section 109 of the Act "the Administrator may not consider economic and technological feasibility in setting air quality standards . . . [because] of a deliberate decision by Congress to subordinate such concerns to the achievement of health goals." *Lead Industries, supra* at 33. In a lengthy analysis of the Act and its legislative history we concluded that the "technology-forcing" requirements of the Act were expressly designed to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible. *Lead Industries, supra* at 34-35.

API's other argument is that the standards are not suported by substantial evidence. We reject this argument because the record is replete with support for the final standards. The studies discussed in the criteria document constitute a rational basis for the finding that adverse health effects occur at ozone levels of 0.15 to 0.25 ppm for sensitive individuals. We need not find that each study discussed in the criteria document is accurate and reliable. The proper function of the court is not to weigh the evidence anew and make technical judgments; our role is limited to determining if the Administrator made a rational judgment. We find that the Administrator's conclusion that normal body functions are "disrupted" at low ozone levels, 44 Fed. Reg. 8213 (1979), is supported by the studies of DeLucia and Adams (effects at 0.15 to 0.30 ppm) (J.A. Ex. 1 at 9-18), Hazucha (effects at 0.25) (J.A. Ex. 1 at 1-15), Wayne (effects at 0.15) (J.A. Ex. 1 at 10-57), Herman (effects at 0.15 to 0.39) (J.A. Ex. 1 at 1-22-23), among others indicated in the record. The court finds no reason to hold that the Administrator abused his discretion in crediting the various studies relied on, even given the acknowledged uncertainties in some of the conclusions. The Administrator noted that "a clear threshold of adverse health effects cannot be identified with certainty for ozone." 44 Fed. Reg. 8213 (1979). Because the Administrator acknowledged the uncertainty of his task and made a rational judgment, we cannot second-guess his conclusion. *Lead Industries, supra,* at 25-28; *See Motor & Equipment Manufacturers Ass'n v. EPA*, 201 U.S. App. D.C. 109, 119-20, 627 F.2d 1095, 1105-06 (1979), *cert. denied,* 446 U.S. 952 (1980); *Hercules, Inc. v. EPA*, 194 U.S. App. D.C. 172, 598 F.2d 91 (1978).

Houston's argument that because natural factors make attainment impossible the Administrator acted arbitrarily and capriciously in setting the primary ozone standard at an "unattainable" level is addressed in part by our analysis of API's attainability argument. Attainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards. *Lead Industries, supra* at 32-33. Further, the agency need not tailor national regulations to fit each region or locale. *NRDC v. EPA*, No. 79-1639 (D.C. Cir. May 7, 1981) slip op. at 34. We also note that compliance extensions are available in some cases, 42 U.S.C. § 7501(a)(2) (Supp. III 1979), and that Congress is aware that some regions are having difficulty in meeting the national standards. *See* 42 U.S.C. § 7501, *et seq.* (Supp. III 1979) (Part D of Title I, setting special requirements for states which have not met standards).

Houston also contends that EPA's strategies for deducing ozone concentrations rely on a faulty premise: that ozone is caused in part by high concentrations of hydrocarbons in the air. In arguing this point Houston relies on a study which allegedly establishes that reduction of hydrocarbon levels will not reduce ozone levels.[8]

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[8] Houston also appended to its brief as Exhibit A a recent study which it contends supports its position in this regard. That exhibit is not part of the record and cannot undercut the Administrator's conclusions on review. 42 U.S.C. § 7607(d)(7)(A) (Supp. III 1979); *see* American Petroleum Institute v. Costle, 197 U.S. App. D.C. 254, 609 F.2d 20 (1979).

The study in question was considered by EPA and rejected on several grounds which undercut the reliability of its conclusions. 44 Fed. Reg. 8235 (1979). Because control of ozone by reduction of hydrocarbon levels is an established methodology (J.A. Ex. 1 at 1-2, 1-3) and because Houston's record evidence in rebuttal is sparse, we cannot find that the Administrator is wrong on this issue.

Petitioner Commonwealth of Virginia challenges the method which EPA selected to measure compliance with the primary standard. The method chosen by EPA measures the highest average ozone level in any one hour to determine compliance. 44 Fed. Reg. 8217-18 (1979). Virginia argues that it would be better to use a daily average ozone level to measure exposure. We find that the Administrator's selection of the maximum hourly average method is reasonable because it is calculated to measure the maximum exposure, which has been found to be a relevant factor in determining the likely consequences of ozone exposure.

Petitioner National Resources Defense Counsel argues that the Administrator has abdicated responsibility for regulation of photochemical oxidants other than ozone by relabeling the regulations here at issue. In 1971 when the first air quality standards were promulgated, the title of the regulation was "National primary and secondary ambient air quality standards for photochemical oxidants". 36 Fed. Reg. 8187 (1971). The title was somewhat misleading because the 1971 standards applied only to ozone, which was the sole photochemical oxidant measured for compliance. 43 Fed. Reg. 26967 (1978). The new standards challenged in this case expressly apply only to ozone and do not attempt to establish permissible levels for other photochemical oxidants. 43 Fed. Reg. 26985 (1978).

Despite NRDC's characterization of the Administrator's action, it appears that EPA has not abandoned its statutory responsibility to regulate pollutants which "may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. § 7408(a)(1)(A) (Supp. III 1979). Rather, the Administrator has chosen to regulate the photochemical oxidant (ozone) that, in his judgment presents a predictable danger. (J.A. Ex. 1 at 1-31) The setting of the ozone standard is not the only action taken by the agency with regard to photochemical oxidants; research concerning the less well known oxidants continues. 44 Fed. Reg. 8204 (1979). The Administrator's approach to photochemical oxidants is reasonable, given the uncertain information concerning the class as a whole.

NRDC also argues that the Administrator failed to establish an adequate margin of safety in the primary standard. As required by the statute, the Administrator promulgated air quality standards that are calculated to "protect individuals who are particularly sensitive to the effects of pollution." *Lead Industries, supra,* at 43. In setting margins of safety the Administrator need not regulate only the known dangers to health, but may "err" on the side of overprotection by setting a fully adequate margin of safety. *See Environmental Defense Fund v. EPA,* 194 U.S. App. D.C. 143, 161-62, 598 F.2d 62, 80-81 (1978). Of course the Administrator's conclusions must be supported by the record, and he may not engage in sheer guesswork. Where the Administrator bases his conclusion as to an adequate margin of safety on a reasoned analysis and evidence of risk, the court will not reverse. NRDC argues that the Administrator erred in setting a primary standard that does not protect sensitive individuals against easily predicted risks. In so arguing NRDC essentially ignores the mixed results of the medical studies evident in the record, choosing instead to rely only on the studies that favor its position. The Administrator, however, was required to take into account all the relevant studies revealed in the record. Because he did so in a rational manner we will not overrule his judgment as to the margin of safety.

The Administrator concluded that the medical evidence "suggest[ed] the real possibility of significant human adverse health effects below 0.15 ppm. Consequently . . . [he] determined that a standard of 0.12 ppm is necessary and is sufficiently prudent unless and until further studies demonstrate reason to doubt that it adequately protect public health". 44 Fed. Reg. 8217 (1979). Having determined that the "probable level for adverse effects in sensitive persons is in the range of 0.15-0.25 ppm", 44 Fed. Reg. 8216 (1979), the Administrator considered the evidence in the record that related to less predictable risks of ozone exposure, a relevant consideration in setting margins of safety. The Administrator considered the lack of medical evidence concerning especially sensitive persons, the possibility that ozone and other pollutants might combine to create cumulative effects, the significance of long-term exposure to otherwise safe ozone levels, inconclusive studies indicating very low ozone damage thresholds, and uncertainties arising from meterological and calibration errors in measurements. *Id.* The Administrator also indicated that the results of the risk assessment study, described at page 4, *supra*, did not support any safety margin above 0.12 ppm. 44 Fed. Reg. 8217 (1979). Given the nature of the task assigned to the Administrator, which is to make an informed judgment based on available evidence, we find that the Administrator's selection of a margin of safety is rational. *See Lead Industries, supra* at 62.

V.

PROCEDURAL CHALLENGES

Petitioners allege numerous procedural errors: EPA's relationship with the Science Advisory Board (SAB) and

Advisory Panel on Health Effects of Photochemical Oxidants (Shy Panel), post-comment period contacts between EPA and the White House, exclusion of documents from the record, and last-minute additions to the record by EPA.

Under the procedural provisions of the Clean Air Act, 42 U.S.C. § 7607(d), we may invalidate the ozone standard because of procedural error only if (1) the agency's failure to observe procedural requirements was arbitrary and capricious, (2) an objection was raised during the comment period, or, where the grounds for such an objection arose after the comment period and the objection is of "central relevance to the outcome of the rule," the objection was raised on a petition for reconsideration before the agency, and (3) "the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made." 42 U.S.C. § 7607(d)(7) & (8). As we noted in *Sierra Club v. Costle*, *supra* at 183, "[t]he essential message of so rigorous a standard is that Congress was concerned that EPA's rulemaking not be casually overturned for procedural reasons, and we of course must respect that judgment."

1. *Science Advisory Board (SAB)*

API and Houston contend that in promulgating the ozone standards EPA violated section 8(e) of ERDDAA, 42 U.S.C. § 4365(e) (Supp. III 1979) by failing to obtain approval of the criteria document from the SAB and to submit the proposed standards to the SAB for review. Section 8(e) provides, in relevant part, that

> (e)(1) The Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the Clean Air Act . . . is provided to any other Federal agency for formal review and comment, shall *make available* to the [Science Ad-

> visory] Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information . . . .
>
> (2) The Board *may make available* to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession. (Emphasis supplied)

The language of the statute indicates that making a proposed criteria document and standard available to the SAB for comment is mandatory but that SAB approval is not required before proceeding to the final stage of rulemaking. This interpretation is supported by the Conference Report underlying this provision of the ERDDAA, which states in pertinent part that

> The Science Advisory Board is intended to be advisory only. The Administrator will still have the responsibility for making the decisions required of him by law. The reviews and comments of the Board are to be provided to the Administrator for his use. . . .

H.R. REP. No. 95-722, 95th Cong., 1st Sess. 16 (1977). While "the intent of [the statutory] language is to insure that the Board is able to comment in a well-informed manner on any regulation that it so desires", "it should not be mandatory that they comment on all proposed regulations. . . ." *Id.* at 17 and 16. In short, the EPA was required under ERDDAA to submit the criteria document and standard to the SAB for comment, but it was not obligated to obtain SAB approval of either before promulgation of a final standard.

The parties do not dispute that EPA submitted two drafts of the criteria document to the SAB and that substantial revisions were requested by the Board. The SAB agreed to cast ballots indicating approval or disapproval of the document based upon a third draft of only the "summary and conclusions" chapter of the document. After submission of the chapter, six of the eleven members of the SAB voted to approve the document subject to (1) stated reservations and (2) the assumption that the revised chapter accurately reflected corresponding changes in the entire document. (J.A. at 289-306) Two SAB members found the document unacceptable, and the remaining three said that they were unable to make a judgment at that time. *Id.* The petitioners contend that the final criteria document, which was never submitted to the SAB, did not incorporate the changes requested by the Board, while EPA argues that the final criteria document adequately addressed the SAB's concerns.

The EPA action does not constitute a violation of section 8(e) of the ERDDAA. The Act requires only that the EPA submit the criteria document to the Board for advice and comment; it does not require that the Administrator obtain approval of the SAB or incorporate all suggested changes. While it might have been preferable for the EPA to have submitted the final criteria document to the SAB, we note that the SAB itself agreed to the course followed. (J.A. Ex. 2 at 563, 578) Given the extent of SAB comment on the criteria document, we cannot find that the document was not "made available" to the Board within the meaning of Section 8(e).

The proposed ozone standard, on the other hand, was never made available to the Board for advice and comment. Section 8(e) makes the submission of any proposed standard to the SAB mandatory. EPA contends that because the standard is based on the criteria document, submission of the standard to the SAB would have been redundant. This argument is unpersuasive; the statute explicitly mandates that standards be submitted to the Board for review. Accordingly, the failure to submit the standards was a violation of procedure required by law. We cannot find, however, that this error was "so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed" had the proposed standards been submitted to the SAB. 42 U.S.C. § 7607(d)(8). The final standard of 0.12 ppm represents an allowance for a margin of safety in light of the adverse health effects range stated in the criteria document (0.15-0.25 ppm). Because any SAB review of the standard would have involved review of the criteria document, i.e., the scientific and technical basis for the standard, we cannot hold that the standard would likely have been significantly changed had it been submitted to the Board. The Administrator's final standard, as noted *supra* at 8, is rational and supported by the record. Although the failure to submit the proposed standards to the SAB was a violation of section 8(e) of the ERDDAA, the circumstances indicate that the error was not so central as to constitute grounds for invalidating the final standards.

2. *Shy Health Effects Panel and Risk Assessment Study*

API and Houston also argue that the EPA Advisory Panel on Health Effects of Photochemical Oxidants (Shy Panel) was an advisory committee within the meaning of the Federal Advisory Committee Act (FACA). 5 U.S.C. app. I, § 1 *et seq.* (Supp. I 1977). Petitioners assert that because EPA failed to observe several requirements of FACA, the actions of the Shy Panel and the EPA reliance on the panel's risk assessment study require invalidation of the standard.

In early 1977 EPA officials responsible for developing the ozone standard asked Dr. Carl Shy of the Institute for Environmental Studies, University of North Carolina at Chapel Hill, to head a panel of paid environmental experts which would prepare "a detailed report on the translation of health data into an ambient air quality standard for photochemical oxidants." (Br. of API at 20) Dr. Shy was a leading advocate of the existing 0.08 ppm ozone standard. *Id.* The panel met privately on June 7 and 8, 1977. A first draft of the panel report, co-authored by Shy and an EPA official, strongly endorsed the existing 0.08 standard. Following some minor revisions, the final draft of the Shy Panel report was submitted to the EPA in late 1977, made available for public comment in December 1977, and placed in the rulemaking docket on March 22, 1978. (Br. of EPA at 126) The report, which used a "risk assessment" technique to conclude that 0.08 ppm was the proper ozone standard, was made part of the criteria document and cited as one of the bases for the final 0.12 ppm standard. (Br. of API at 29)

The FACA defines an advisory committee, in relevant part, as "any . . . panel . . . which is . . . established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for . . . one or more agencies . . . ." 5 U.S.C. app. § 3(2)(C). Petitioners contend that because the Shy Panel clearly is an advisory committee within the meaning of this provision, the conduct of the panel violates several provisions of FACA and that EPA reliance on the panel's study as a basis for the final rule requires invalidation of the standard. For example, it is argued that the choice of a known partisan to chair the panel violates the FACA requirements that the committee be "fairly balanced" and that it not be "inappropriately influenced" by any "special interest." 5 U.S.C. app. § 5(b)(2)-(3). It is also asserted that the private meetings of the panel violate the FACA requirement that public notice and opportunity for public participation be given. 5 U.S.C. app. §§ 10(a)(2) and (d)(3). EPA asserts, on the other hand, that the Shy Panel is not subject to FACA because the group consisted of paid consultants and the legislative history of

FACA indicates that the Act was not intended to apply to persons having contractual relationships with the government. CONF. REP. No. 92-1403, 92d CONG., 2d SESS. (1972). *See Lombardo v. Handler*, 397 F. Supp. 792 (D.D.C. 1975), *aff'd mem.*, 178 U.S. App. D.C. 277, 546 F.2d 1043 (1976), *cert. denied*, 431 U.S. 932 (1977). In any event, argues EPA, none of the Shy Panel actions violated FACA.

We need not reach the questions whether the Shy Panel was an advisory committee within the meaning of FACA and whether violations of FACA occurred. Even were we to find that the panel was subject to FACA, that violations of the Act occurred, and that reliance on the risk assessment study was therefore illegal, we would not be able to say that there is a substantial likelihood that the 0.12 ppm standard would have been significantly different if such errors had not been made. The ultimate adoption of a 0.12 ppm standard constitutes a rejection of the Shy Panel's conclusion that the ozone standard should not be relaxed. Moreover, even though the Shy Report was cited as one of the bases for the final standards, the criteria document otherwise fully supports the 0.12 ppm standard as a figure representing a margin of safety below the 0.15-0.25 ppm danger zone. In short, absent the Shy Panel report, there is a substantial likelihood that the standard would have been the same. We therefore cannot invalidate the standard based on the alleged procedural irregularities.

3. *EPA Exclusion of API Submission Regarding Natural Hydrocarbons*

API asserts that the EPA erred in failing to consider and by excluding from the docket and record an API post-comment period submission concerning natural organic emissions from vegetation.

Section 307(d)(4)(B) of the Clean Air Act, 42 U.S.C. § 7607(d)(4)(B) requires the Administrator to place in the docket all documents, even those not submitted during the comment period, determined to be "centrally relevant" to the rulemaking. API, in submitting the above documents, noted in its request that they related to the issue of whether "attainment of the proposed standards would be precluded in most areas of the nation by natural background levels of ozone resulting in part from natural hydrocarbon emissions." (J.A. at 1003) EPA refused to docket most of the documents submitted by API on the ground that the question of attainability is not relevant to the setting of ambient air quality standards under the Clean Air Act. As noted, *supra* at 10, the EPA position that attainability is not central to a rulemaking of this type is correct. Accordingly, EPA's decision to exclude the API submission was proper.

4. *EPA's Last-Minute Addition to the Record*

Finally, NRDC contends that EPA violated the administrative procedure requirements of the Clean Air Act by placing in the record, after the close of the comment period and one day before promulgation of the final rule, an EPA staff paper entitled "Evaluation of Alternative Secondary Ozone Air Quality Standards". The statement accompanying the final rule indicated that this study was the primary basis for the change from an 0.08 ppm to 0.12 ppm secondary standard. 44 Fed. Reg. 8217 (1979). NRDC argues that the failure to give notice or opportunity to comment on any analysis so central to the final decision warrants invalidation of the secondary standard.

The last-minute addition to the record of a study which constituted the basis for the final secondary standard is disturbing. The study was never exposed to public scrutiny or comment. However, the procedural requirements of the Clean Air Act do not permit NRDC to raise this objection for the first time on appeal. *See Oljato Chapter of the Navajo Tribe v. Train,* 169 U.S. App. D.C. 195, 207-08, 515 F.2d 654, 666-67 (D.C. Cir. 1975). Section 307(d)(7)(B) of the Act, 42 U.S.C. § 7607(d)(7)(B) provides that:

> (B) Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the ground for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b) of this section). Such reconsideration shall not postpone the effectiveness of the rule. The effectiveness of the rule may be stayed during such reconsideration, however, by the Administrator or the court for a period not to exceed three months.

The statute states that before this court may review a procedural objection the parties must raise the objection on petition for reconsideration before the EPA when the grounds for such objection "arose after the period for public comment (but within the time specified for judicial review". This reading is confirmed by the legislative history of this provision, which states in pertinent part:

> Section 307(d)(7)(B) would specify the circumstances in which a reviewing court may consider

> data and arguments that were not presented to the agency during the rulemaking. Even in such cases, however, the Agency must first be given an opportunity to pass on the significance of the materials and determine whether supplementary proceeding [sic] are called for or not. Thus, the committee bill confirms the court's decision in *Oljato Chapter of the Navajo Tribe v. Train*, 515 F.2d 654 (D.C. Cir. 1975).

H.R. REP. 95-294, 95th CONG., 1st SESS. 323 (1977). *See generally, Sierra Club v. Costle, supra* at 193-94.

The record before us does not suggest that any party, including NRDC, filed petitions for reconsideration with the EPA. The grounds for NRDC's objection were clear as of the date of promulgation of the final rule. Had NRDC complied with the statutory requirement of filing a petition for reconsideration, it could have commented on the staff study and the EPA could have responded during the period when the petition was pending. Because the required petition for reconsideration was never filed, we cannot reach the merits of the NRDC objection. *See generally, Sierra Club v. Costle, supra* at 200-201 & n.497.

Although we refer to a "petition for reconsideration" in this opinion, it should be noted that any formal communication to the Administrator that specifically states an objection, requests reconsideration of Agency action because of the objection, and provides notice to interested parties, would satisfy the statutory requirement for an "objection . . . raised with reasonable specificity." 42 U.S.C. § 7607(d)(7)(B). The record reflects no such formal communication from NRDC.

5. *Post-Comment Period White House Contacts*

NRDC contends that a series of post-comment period oral contacts between officials of the EPA and the White House and its agencies were not documented in the docket or the record. NRDC argues that this constitutes a violation of Clean Air Act Section 307(d)(4)(B)(ii), 42 U.S.C. § 7607(d)(4)(B)(ii) (1976), which provides that:

> (ii) The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

As we have said, a petitioner must raise a procedural objection with the EPA if this court is to consider the objection. 42 U.S.C. § 7607(d)(7)(B). This rule applies even when the grounds for the objection first became known to the petitioner after the comment period ended, but before the period for petitioning for review expired. This is evident from the statute: ". . . if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed." 42 U.S.C. § 7607(d)(7)(B).

According to NRDC, it was alerted to the White House contacts as early as February 26 and 27, 1979, when hearings on executive branch review of environmental regulations were held by the Senate Subcommittee on Environmental Pollution. (NRDC Br. at 19, n.46, 28, n.53) The Subcommittee examined the role of White House economic advisers. The final regulations were published in the Federal Register on February 8, 1979. 44 Fed. Reg. 8202. Thereafter NRDC had sixty days to file its petition for review. 42 U.S.C. § 7607(b)(1). In that period NRDC could have petitioned the EPA for reconsideration based on its objection to the White House contacts. Because NRDC failed to exhaust the administrative remedy specifically required by the Act we may not and do not consider this objection to the Administrator's action. 42 U.S.C. § 7607(d)(7)(B); § 7607(d)(9)(D)(ii).

VI.

CONCLUSION

In summary, we hold that the primary and secondary standards for ozone emission are supported by a rational basis in the record. Although the EPA procedures were not a model of regulatory action, we hold that none of the alleged procedural errors warrants invalidation of the final standards.

Affirmed.

Wald, *Circuit Judge*, dissenting in part: I concur in all respects with Judge Robb's majority opinion, save one: I am troubled by the manner in which the court refuses to decide the *ex parte* issue for failure to raise it properly under section 307.

The majority opinion disposes of NRDC's challenge concerning post-comment period White House contacts by holding that NRDC failed to raise this objection before EPA in a timely manner, and is therefore precluded from doing so here under 42 U.S.C. § 7607(d)(9)(D); § 7607(d)(7)(B). EPA itself, however, nowhere claims such a bar to deciding this issue on the merits, and I find the present record inconclusive on whether this issue was appropriately brought to EPA's attention. I would therefore have posed a single interrogatory to the parties to ascertain whether a timely objection by NRDC was in fact made on this issue so as to bring it within the scope of our review under this statute.

As the majority recognizes, the relevant section, 42 U.S.C. § 7607(d)(7)(B), requires only an "objection [of central relevance] . . . raised with reasonable specificity" to require the Administrator to convene a proceeding for reconsideration.

While we may be confident here that any *formal* petitions for reconsideration would appear in the record, we cannot be as sure about the presence of other, less formal objections to the rulemaking. The latter would *not* necessarily appear in the record on appeal, because the record for judicial review as defined in section 307(d)(7)(A) does not include all post-promulgation objections. It is also possible that an objection made to the alleged *ex parte* contacts even before promulgation might not have been placed in the record as being "centrally relevant."

Without more reliable knowledge that no reasonably specific, timely objection was made by NRDC regarding post-comment period communications, I would not find the issue barred in this court without some statement by the parties addressing this point. My suspicion that an appropriate objection may in fact have been made is fueled by (1) Environmental Defense Fund testimony in the February, 1979 hearings before the Senate Subcommittee on Environmental Pollution,[1] that it had written Administrator Costle two weeks before about White House-EPA *ex parte* contacts; and (2) EPA's own failure to object to NRDC's claims on the ground that the claims were not properly raised before the agency. EPA, in fact, defends exclusively on the merits, asserting that the post-comment period White House communications were proper and duly recorded. *See* Brief for Respondent EPA at 101-10.

In short, I do not think it reasonable to assume, on the record before us and in the absence of any such assertion by EPA, that no timely objection was made on the *ex parte* issue. I would instead have resolved this factual ambiguity in the record before deciding whether to pass on the merits of the *ex parte* issue.

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[1] *See* Executive Branch Review of Environmental Regulations: Hearings Before the Subcomm. on Environmental Pollution of the Senate Comm. on Environment and Public Works, 96th Cong., 1st Sess. 57 (Feb. 26, 1979) (testimony of Robert Rauch, Staff Attorney, Envt'l Def. Fund).

APPENDIX B

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 79-1104

AMERICAN PETROLEUM INSTITUTE, PETITIONER *

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, AND
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENTS *

AMERICAN PETROLEUM INSTITUTE and 15
of its member companies
CHEMICAL MANUFACTURERS ASSOCIATION
THE ST. LOUIS REGIONAL COMMERCE &
GROWTH ASSOCIATION
NATIONAL RESOURCES DEFENSE COUNCIL, *et al.*
THE STATE OF OKLAHOMA
E.I. DU PONT DE NEMOURS & CO.
INTERVENORS

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* Consolidated with the following cases (identified by this Circuit's case number and petitioner), in all of which the Environmental Protection Agency is the respondent: No. 79-1201, E. I. Du Pont De Nemours and Company; No. 79-1222, American Petroleum Institute, et al.; No. 79-1290, Chemical Manufacturers Association; No. 79-1335, The

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

On Petitioners' Motion to Correct the Record

Filed November 6, 1979

Edward W. Warren, Robert F. Van Voorheer, John S. Hahn, Robert R. Bonzcek, Bernard J. Reilly, Carl B. Everett, John H. Pickering, Andrew T. A. Macdonald and *David R. Johnson* were on the motion to correct the record, for petitioners American Petroleum Institute, et al. in Nos. 79-1104, 79-1201, 79-1222, 79-1290, 79-1359 and 79-1370 and intervenors in Nos. 79-1335, 79-1356 and 79-1362.

Patrick J. Cafferty, Attorney, Department of Justice, was on the opposition to motion to correct the record, for respondent, Environmental Protection Agency.

Richard E. Ayres, Peter J. Herzberg and *David D. Doniger* were on the opposition to motion to correct the record, for intervenor National Resources Defense Council, et al. in No. 79-1104 and petitioner in Nos. 79-1335 and 79-1362.

Also *Joseph J. Brecher* and *Peter J. Herzberg* entered appearances, for petitioner Sierra Club in No. 79-1356.

Also *Frederick S. Fisher, James E. Ryan, Jr.* and *Roger L. Chaffe* entered appearances for petitioner Commonwealth of Virginia, et al. in No. 79-1365.

Natural Resources Defense Council, Inc., et al.; No. 79-1356, Sierra Club; No. 79-1359, Chemical Manufacturers Association, et al.; No. 79-1362, The Connecticut Lung Association, Inc.; No. 79-1365, Commonwealth of Virginia, ex rel., The State Air Pollution Control Board; No. 79-1367, City of Houston, Texas; No. 79-1370, American Petroleum Institute, et al.

Also *Daniel Joseph* and *Courtenay Ellis* entered appearances, for petitioner City of Houston, Texas, in No. 79-1367.

Also *Jeffrey O. Cerar,* Attorney, Environmental Protection Agency, entered an appearance for respondents.

Also *Christopher S. Bond* and *Charles A. Blackmar* entered appearances for intervenor The St. Louis Regional Commerce, et al. in No. 79-1104.

Also *Charles S. Rogers,* Assistant Attorney General for the State of Oklahoma entered an appearance for intervenor, State of Oklahoma ex rel George Nigh, etc. in No. 79-1104.

Before: MCGOWAN,* LEVENTHAL and WALD, *Circuit Judges.* Opinion *per curiam.*

Per curiam: This motion to correct the record is part of an action challenging the primary and secondary national ambient air quality standards for ozone, recently promulgated by the Environmental Protection Agency (EPA) and published at 44 FED. REG. 8202, February 8, 1979. The standards are challenged by a group of industry petitioners,[1] who contend that the standards are unrealistically strict, and by a group of environmentalist and health petitioners,[2] who contend that they are not strict enough. This opinion concerns one of several motions by the parties to supplement or correct the record. We do not intimate any views as to the merits of the case.

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* Circuit Judge McGowan did not participate in this decision.

[1] The industry petitioners are American Petroleum Institute and its member companies, Manufacturing Chemists Association and its member companies, and E. I. duPont de Nemours & Co.

[2] The environmentalist petitioners are the National Resources Defense Council, Sierra Club, American Lung Association, Delaware Valley Citizens' Committee for Clean Air, and Connecticut Lung Association.

I. Background

The industry petitioners have moved that this court order the EPA to remove from the record for judicial review certain documents placed in the record after the Administrator publicly signed and announced the ozone standards on January 26, 1979, but before they were published in the Federal Register on February 8, 1979. They contend that these materials[3] were included in the record in contravention of the record-compilation requirements of Section 305(a) of the Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685, 772-776. These amendments added a new Section 307(d) to the Clean Air Act, 42 U.S.C. § 7607(d) (Supp. I 1977).

The purpose of the amendments was to facilitate judicial review by defining "what the record for a rule consists of, and how and when material must be placed in the record." H.R. Rep. No. 294, 95th Cong., 1st Sess. 318, 319 (1977). The statute requires the inclusion of some materials, and the exclusion of others, so that the record for judicial review will comprise only those materials directly pertinent to the agency's decision. In summary, it requires the EPA to compile a docket on or before the date a proposed rule is published in the Federal Register. The materials in the docket must be open to public inspection until the final rule is promulgated, and, with one exception,[4] they become the record for judicial review after such promulgation. The docket must include the proposed rule, a statement of its basis and purpose (including a summary of the factual data on which the proposed rule is based, the methodology used with the respect to those data, and the major legal interpretations and policy considerations underlying the rule), all comments written by the public and submitted during the comment period, a transcript of any public hearing on the proposed rule, the text of the final rule, a statement of the basis and purpose of the final rule, an explanation of major changes from the proposed rule, and a response to every major comment, criticism, and new datum submitted during the comment period.

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[3] The documents at issue are: document Nos. IIA-B-1 through 5 ("Studies or Contractor Reports" prepared on various dates, placed in docket on February 6, 1979, concerning health effects or eye irritation from ozone, photochemical smog pollution, and other substances); IIB-E-7 (a comment written after the comment period by Roger Randolph of the Tulsa City-County Health Dept. concerning the calibration issue, one of many comments on the subject, placed in docket on January 31, 1979); and IV-G-40 through 55, and 58 through 61 (comments from the public on the ozone standards, written after the close of the comment period, and docketed after January 25, 1979). The EPA neither referred to nor apparently relied upon those documents in reaching its decision.

In addition, the EPA may supplement the docket with any public comments received after the comment period or other document that becomes available after publication of the proposed rule. These additional materials may be added to the docket if the Administrator determines they are "of central relevance to the rulemaking." The statute requires that such materials, as well as comments submitted during the comment period, be placed in the docket "as soon as possible after their availability." Section 307(d)(4)(B)(i), 42 U.S.C. § 7607(d)(4)(B)(i) (Supp. I 1977).

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[4] Documents generated by the review of the rule by the Office of Management and Budget and other federal agencies must be available to the public in the rulemaking docket, but they are excluded from the record for judicial review. Section 607(d)(7)(A), 42 U.S.C. § 7607(d)(7)(A) (Supp. I 1977).

In addition, the statute provides: "The promulgated rule may not be based (in part or whole) on any information or data which has not been placed in the docket as of the date of such promulgation." Section 307(d)(6)(C), 42 U.S.C. § 7607(d)(6)(C) (Supp. I 1977). All the parties to this case agree that this means that no additional materials—other than those *required* by the statute and wrongfully omitted by the EPA—may be added to the docket after the rule is promulgated. The record presented to the court on a petition for review thus consists of materials required by the statute to be included in the docket supplemented by materials "of central importance to the rulemaking" placed in the docket prior to promulgation of the rule.

We do not decide in this opinion whether other materials not specified by the statute to be included in the record, but necessary for the court to make a complete review of the decision, may be included in a supplemental record for judicial review. All we decide today is when the "date of such promulgation" occurs for purposes of the record cut-off of Section 307(d)(6)(C).

II. ANALYSIS

The issue in this case is whether the "date of such promulgation" means the date that the rule is signed and distributed to the press and public, or the date that the rule is published in the Federal Register. The word "promulgation" is not defined in the statute, nor is there an explicit definition in the legislative history. Both sides seek to bolster their arguments by reference to a 1977 amendment to another section of the Clean Air Act, Section 307(b)(1). The 1970 version read:

> Any such petition [for review] shall be filed within 30 days from the date of such promulgation or approval, or after such date if such petition is based solely on grounds arising after such 30th day.

As amended, Section 307(b)(1)[5] reads:

> Any petition for review under this subsection shall be filed within sixty days from the date notice of such promulgation, approval, or action appears in the Federal Register * * *.

The House Report concerning amendments to this section, H.R. Rep. No. 294, 95th Cong., 1st Sess. 322 (1977), explains that this change was intended to make clear that the time for filing a petition for review begins to run from the time of publication in the Federal Register, rather than from the date the Administrator signs the rule and transmits it for publication.

The EPA and the environmentalist petitioners contend that this change shows that Congress meant by "date of such promulgation" the date of publication in the Register. In contrast, the industry petitioners contend that Congress has deliberately created a distinction between the date of "promulgation" and the date of publication in the Register. Although the industry petitioners' argument seems somewhat the stronger, we are not willing to decide this issue on so flimsy an indication of congressional intent.

The statute must be interpreted in accordance with its context and purpose. This has been the course followed by this court in the past in deciding when "promulgation" or "issuance" of a rule occurs. *See, e.g., Industrial Union Dept. v. Bingham*, 570 F.2d 965 (D.C. Cir. 1977); *Microwave Communications, Inc. v. FCC*, 515 F.2d 385 (D.C. Cir. 1974); *Saturn Airways, Inc. v. CAB*, 476 F.2d 907 (D.C. Cir. 1973). The main purpose of the record cut-off provision of Section 307(d)(6)(C) was to ensure that the rulemaking process would be reviewed on the basis of data and reasoning that were available to EPA at the time the decision was being made and that were deemed important at that time. Pederson, *Formal Records and Informal Rulemaking*, 85 YALE L.J. 38, 74-78 (1975).[6]

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[5] Now codified at 42 U.S.C. § 7607(b)(1) (Supp. I 1977).

By requiring that the record be in final form when the rule is promulgated, the statute promotes policies that are vital to effective judicial review and long recognized by this and other courts. If all materials relevant to the decision are placed in a publicly available docket promptly upon their receipt by the EPA—rather than assembled after the decisionmaking process is completed—then interested parties will be able to examine them and respond to them. *See Portland Cement Association v. Ruckleshaus*, 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974). Moreover, the creation of a precisely defined and closed administrative record makes it more likely that the agency's decision will be based on the materials in that record, and explained by the agency at the time of promulgation. *See Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168-169 (1962); *International Harvestor Co. v. Ruckleshaus*, 478 F.2d 615, 632 (D.C. Cir. 1973); *Pederson, supra*, at 73-74. The agency will not be tempted to shore up inadequately justified positions by adding *post hoc* rationalizations to the record, nor will it assume at the time it promulgates a rule that there will be an opportunity afterwards to improve the record. In sum, the statute promotes public participation in rulemaking, reasoned decisionmaking based on the record, and judicial review of the agency decision based on the data and reasoning before the agency at the time the decision was made.

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[6] The article by William F. Pederson, Jr., an attorney in the Office of General Counsel of the EPA, may be taken as an authoritative guide to congressional intent in enacting the record provisions of Section 307(d). The House Report on the 1977 amendments to the Clean Air Act states: "By and large, this section [307(d)] represents a legislative adoption of the suggestions for a rulemaking record set forth in a law review article dealing with EPA [citing *Pederson*]." H.R. Rep. No. 294, 95th Cong., 1st Sess. 319 (1977).

These considerations lead to the conclusion that "the date of such promulgation" in Section 307(d)(6)(C) means the date that the rule is signed and released to the public. At that time, the agency's decision is fixed, and no additional data or arguments will change it.[7] After that date, no materials added to the docket could be examined by any members of the public; there would be no opportunity for agency lawyers to insert supportive documents into the record.

The EPA has argued that adoption of the date of publication in the Federal Register as the date of promulgation would "allow[] EPA flexibility to review the documents that were placed in the docket to ensure that all documents which are required by statute to be in the docket have in fact been placed there." Memorandum of Respondents in Opposition to Motion to Correct Record and Motion to Supplement Record at 21. This argument must be rejected. As to documents required by the statute to be included in the record, EPA may—indeed, must—place them in the record when they are available.[8] As to other documents, the purpose of the statute is to *eliminate* the flexibility of the EPA to add such documents after the decision has been made. If EPA wants a document to be considered on judicial review, it must place the document in the rulemaking docket, open to the public, before the rule is signed and announced.

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[7] In this case, the ozone standards were announced to the press and public, and widely distributed in written form to any interested parties. If, as in *Industrial Union Dept. v. Bingham*, 570 F.2d 965 (D.C. Cir. 1977), the decision, after being signed, were released only to a few selected members of the public, other considerations might be present.

[8] If they are erroneously omitted, the agency may follow a reasonable procedure to supplement the record.

The industry petitioners' motion to correct the record by the removal from the record of document Nos. IIA-B-1 through 5, IIB-E-7, IV-G-40 through 55, and IV-G-58 through 61, is granted.

So ordered.

APPENDIX C

Environmental Protection Agency Promulgation of NAAQS for Ozone (44 Fed. Reg. 8202, Feb. 8, 1979)

Title 40 — Protection Of Environment

Chapter I — Environmental Protection Agency

Subchapter C — Air Programs

[FRL 1018-2]

Part 50 — National Primary and Secondary Ambient Air Quality Standards

Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants

AGENCY: Environmental Protection Agency.

ACTION: Final rulemaking.

SUMMARY: In accordance with the provisions of Sections 108 and 109 of the Clean Air Act as amended, EPA has reviewed and revised the criteria upon which the existing primary and secondary photochemical oxidant standards are based. These standards were promulgated in 1971 (36 FR 8186) and were both set at an hourly average level of 0.08 part per million (ppm) not to be exceeded more than 1 hour per year. On June 22, 1978, EPA proposed changes in the standard (43 FR 26962) based on the findings of the revised criteria. The proposed changes included (1) raising the primary standard to 0.10 ppm, (2) retaining the 0.08 ppm secondary standard, (3) changing the chemical designation of the standard from photochemical oxidants to ozone, and (4) changing to a standard with a statistical rather than deterministic form. The final rulemaking will make three further changes in the standard: (1) Raising the primary standard to 0.12 ppm, (2) raising the secondary standard to 0.12 ppm, and (3) changing the definition of the point at which the standard is attained to "when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than one."

EFFECTIVE DATE: This revision is effective immediately upon publication. The normal 30-day delay in effectiveness is not required, when, as in this case, a restriction is eased.

FOR FURTHER INFORMATION CONTACT:

> Mr. Joseph Padgett, Director (MD-12), Strategies and Air Standards Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, Telephone: 919-541-5204 (FTS 629-5204).

AVAILABILITY OF RELATED INFORMATION: A docket (Number OAQPS 78-8) containing information used by EPA in revising the standards is available for public inspection and copying between 8:00 a.m. and 4:30 p.m. Monday through Friday, at EPA's Central Docket Section, Room 2903 Waterside Mall, 401 M Street, SW, Washington DC 20460. These materials include the "Air Quality Criteria for Ozone and Other Photochemical Oxidants" and "Control Techniques for Volatile Organic Emissions from Stationary Sources," both of which were issued simultaneously when this standard was proposed. The control techniques document and staff papers pertaining to the form of the ozone standard, risk assessment method, secondary standard, and health panel assessment are available upon request from Mr. Joseph Padgett. Statements of the environmental, economic, and energy impacts of implementing this standard revision are also available upon request from Mr. Joseph Padgett, at the address shown above. The air quality criteria document can be obtained from: Mr. Michael Berry (MD-52), Environmental Criteria and Assessment Office, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, Telephone: 919-541-2266 (FTS 629-2266).

This preamble describes revisions to 40 CFR Part 50, Appendix H, "Interpretation of the National Ambient Air Quality Standards for Ozone," and Appendix D, "Measurement Principle and Calibration Procedure for the Measurement of Photochemical Oxidants Corrected for Interferences Due to Nitrogen Oxides and Sulfur Dioxide," that are related to the revision of the air quality standard for ozone. In addition, elsewhere in this issue of the FEDERAL REGISTER EPA is promulgating revisions to 40 CFR Part 50, Appendix D, replacing (superseding) the current calibration procedure with a new, superior calibration procedure based on ultraviolet photometry.

Revisions to 40 CFR Part 51, substituting the word "ozone" for "photochemical oxidants" throughout that part, and to Section 51.14, pertaining to control strategies, are being promulgated by EPA elsewhere in this issue of the FEDERAL REGISTER.

SUPPLEMENTARY INFORMATION:

BACKGROUND

On April 30, 1971, the Environmental Protection Agency promulgated in the FEDERAL REGISTER (36 FR 8186) National Ambient Air Quality Standards for photochemical oxidants. The scientific, technical, and medical bases for these standards are contained in the air quality criteria document for photochemical oxidants, published by the U.S. Department of Health, Education, and Welfare in March 1970. Both the primary and secondary standards were set at an hourly average level of 0.08 ppm not to be exceeded more than once per year. The asthma study cited as evidence for the original standard is based on work by Schoettlin and Landau (1961). As discussed in the June 22, 1978, proposed revision to the original standard, EPA has reassessed its conclusions regarding this study. This reassessment, plus the evaluation of medical evidence accumulated since 1970, led EPA to propose, on June 22, 1978, a revised primary standard of 0.10 ppm (43 FR 26962). EPA did not propose a change in the secondary welfare standard at that time. The proposal was accompanied by publication of revised criteria and control techniques documents, as well as various staff papers relating to the standard itself and to implementation of the standard. EPA solicited written comments on the propsed standard and, to accept oral testimony, sponsored four public hearings (Washington, D.C. — July 18; Atlanta, Ga. — August 17; Dallas, Tex. — August 22; Los Angeles, Calif. — August 24).

Oxidants are strongly oxidizing compounds, which are the primary constituents of photochemical smog. The oxidant found in largest amounts is ozone (O_3), a very reactive form of oxygen. Oxidants also include the group of compounds referred to collectively as peroxyacylnitrates (PANs) and other compounds, all produced in much smaller quantities than ozone.

Most of these materials are not emitted directly into the atmosphere but result primarily from a series of chemical reactions between oxidant precursors (nitrogen oxides and organic compounds) in the presence of sunlight. The principal sources of organic compounds are the hydrocarbon emissions from automobile and truck exhausts, gasoline vapors, paint solvent evaporation, open burning, dry cleaning fluids, chemical plants and other industrial operations. Nitrogen oxides are emitted primarily from combustion sources such as electric power generation units, gas and oil-fired space heaters, and automobile, diesel and jet engines.

The reductions in emissions of nitrogen oxides and organic compounds are achieved through Federal and State programs that have been formalized in regulations promulgated under the Clean Air Act. The Federal programs provide for reduction in emissions nationwide through the Federal Motor Vehicle Control Program, the Federal program for control of aircraft emissions, National Emission Standards for Hazardous Air Pollutants, and the development of New Source Performance Standards. The State programs provide for additional control measures through State Implementation Plans in those areas of the country where the Federal programs are not sufficiently stringent to permit attainment of air quality standards.

LEGISLATIVE REQUIREMENTS AFFECTING THIS PROMULGATION

Two sections of the Clean Air Act govern the development of a National Ambient Air Quality Standard. Section 108 instructs EPA to document the scientific basis (criteria) for the standard, and Section 109 provides guidance on establishing standards and reviewing the criteria.

Air quality criteria are required by Section 108(a)(2) to reflect accurately the latest scientific information useful in indicating the kind and extent of all identifiable effects on public health or welfare that may be expected from the presence of the pollutant in the ambient air.

The Administrator is required to propose, simultaneously with the issuance of these criteria, primary and secondary ambient air quality standards based upon such criteria. The primary standard is defined in

Section 109(b)(1) as the ambient air quality standard the attainment and maintenance of which in the Administrator's judgment, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. The secondary standard (Section 109(b)(2) must specify a level the attainment and maintenance of which in the Administrator's judgment, based on such criteria, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. These adverse welfare effects, which are discussed in Section 302(h) of the Act, include effects on soils, water, crops, vegetation, man-made materials, animals, weather, visibility, hazards to transportation, economic values, personal comfort and well-being, and other factors.

The Clean Air Act specifies that primary National Ambient Air Quality Standards are to be based on scientific criteria relating to the level that should be attained to protect public health adequately. Considerations of cost of achieving those standards or the existence of technology to bring about needed reductions of emissions are not germane to such a determination, as the words of the Act and its legislative history clearly indicate. Section 109(d) directs the Administrator to complete a review of all existing standards and criteria before the end of 1980 and at 5-year intervals thereafter and to revise them in whatever manner that review reveals is necessary. This promulgation is the result of such a review.

Assuring attainment and maintenance of ambient air quality standards is the responsibility of the States. Under section 110 of the Act, they are to submit to EPA for approval State Implementation Plans (SIPs) that provide for the necessary legal requirements for sources of the relevant pollutant so as to demonstrate attainment and maintenance of the standards by certain deadlines. In many areas of the country the ambient air quality standards are not being attained, despite the fact that the deadline for attainment has long since passed. As a remedy, Part D of the Act requires states with violations of ambient air quality standards to submit revised SIPs to ensure attainment of the standards and to meet certain new requirements of Part D by January 1, 1979. (Section 129(c), Pub. L. 95-95, note under 42 U.S.C. 7502.) The Act does not authorize the Administrator to extend that deadline, and consequently this revision of the photochemical oxidant standard does not affect the deadline for submittal of SIP revisions.

Section 110(a)(1) requires that SIP revisions be submitted within 9 months after a standard is revised. However, this provision refers to situations where a standard is tightened with the result that existing SIPs are no longer adequate to attain and maintain the standard in question. Where a standard is relaxed, no SIP revision is required by the law, since states may have more stringent controls than necessary if they choose.

Furthermore, the change in the chemical species designation of the standard from photochemical oxidants to ozone does not make this standard subject to the provision of section 110(a)(1) cited above. The intent of the standard (total oxidant reduction), the control strategies, and the index of progress toward attainment (measured ozone levels) remain unchanged.

Summary of General Findings From Air Quality Criteria for Ozone and Photochemical Oxidants

On April 20, 1977, EPA announced (42 FR 20493) that it was reviewing and updating the 1970 criteria document for photochemical oxidants in accordance with provisions of section 109(d)(1) of the Clean Air Act as amended. The notice called for information and data that would be helpful in revising the document. In preparing the criteria document, EPA provided a number of opportunities for external review and comment. Two drafts of the document have been made available for external review, and EPA received more than 50 written comments on the first draft and approximately 20 on the second draft. The American Petroleum Institute has submitted extensive information that EPA considered in this standard review. The criteria document was the subject of two meetings of the Subcommittee on Scientific Criteria for Photochemical Oxidants of EPA's Science Advisory Board. Each of these meetings was open to the public, and a number of individuals presented both critical review and new information for EPA's consideration. A full discussion of comments received during the review process, as well as EPA's disposition of these comments, can be found in the docket (OAQPS 78-8) assembled for this rulemaking.

From EPA's review of the scientific information presented in the criteria document, several key areas with particular relevance to setting the ozone standard have emerged:

1. *Threshold concept* — Although the concept of an adverse health effect threshold has utility in setting ambient air quality standards, the adverse health effect threshold concentration cannot be identified with certainty. The lowest concentration which causes measured health effects in a scientific experiment depends on the particular subjects who have been studied because sensitivity to pollutants varies among different members of the population. Only limited studies can be performed on groups of unusually sensitive persons. Most experimental studies of human subjects are performed on small numbers of relatively healthy persons who do not fully reflect the range of human sensitivity. Also, the air to which the subjects are exposed does not include the full mix of chemicals other than the pollutant being studied which are in the ambient air. Some of these chemicals may be additive with the given pollutant in causing the adverse health effect, so that lower levels of the pollutant will result in the effect. Animal exposure studies cannot provide precise models of sensitive human populations. Thus, adverse health effect thresholds for sensitive persons are difficult or impossible to determine experimentally, while the threshold for healthy persons or animals is not likely to be predictive of the response of more sensitive groups. In this notice of rulemaking EPA uses the terminology "probable effects level" to refer to the level that in its best judgment is most likely to be the adverse health effect threshold concentration. It is the fact that the adverse health effect threshold concentration is actually unknown that necessitates the margin of safety required by the Act.

2. *Ozone health effects* — Ozone is a pulmonary irritant that affects the respiratory mucous membranes, other lung tissues and respiratory functions. Clinical and epidemiological studies have demonstrated that ozone impairs the normal mechanical function of the human lung and causes clinical symptoms such as chest tightness, coughing and wheezing. These effects may occur in sensitive individuals, as well as in healthy exercising persons, at short-term ozone concentrations between 0.15 and 0.25 ppm. The clinical studies data base for these effects is far more extensive than that which was available in 1970,

and these effects have now been demonstrated at lower levels than those cited in the 1970 criteria document.

3. *Effects on Asthmatics* — The best available evidence suggests that an elevated proportion of asthmatics experience attacks on days when the peak hourly oxidant concentrations reach about 0.25 ppm. This finding is based on a reevaluation of the study by Schoettlin and Landau (1961).

4. *Toxicologic findings* — The key finding from toxicologic studies is the increased susceptibility to bacterial infection in laboratory animals exposed to 0.10 ppm ozone and a bacterial challenge. Infection rates are lower for animals exposed only to the bacterial challenge. Other effects such as biochemical changes, morphological abnormalities, and genetic changes have been found in some studies of animals exposed to ozone concentrations as low as 0.1 to 0.3 ppm. While the data from animal studies cannot be directly extrapolated to man, they can be taken as indicators of the full range of effects that may occur in humans. The epidemiology study by Durham (1974) that reported increased rates of illness in college students following periods of elevated air pollution levels (with peak oxidant being the pollution variable most strongly associated with illness) further increases our concern regarding the implications for man of the animal study findings.

5. *Ozone effects on aging processes* — A limited amount of data suggests that ozone may accelerate the aging process in living organisms. Exposure of rabbits to unspecified concentrations of ozone for 1 hour per week for a year has been reported to induce premature aging symptoms such as premature cartilage calcification, severe depletion of body fat, and the general signs of aging (Stokinger, 1963).

6. *Pollutant interactions* — The fact that ozone exposure is frequently accompanied by exposure to other pollutants, such as sulfur dioxide (SO_2), has prompted several investigators to conduct laboratory evaluations of exposure of human subjects to combinations of O_3 and other pollutants. Simultaneous exposures to 0.37 ppm O_3 and 0.37 ppm SO_2 were reported to produce larger changes in pulmonary function than exposure to either pollutant alone. No obvious effects were observed in other simultaneous exposure tests using 0.25 ppm

O_3 and 0.3 ppm nitrogen dioxide (NO_2), as well as O_3, NO_2, and 30 ppm carbon monoxide (CO). Nevertheless, the SO_2 - O_3 synergism findings support the need for an adequate margin — of safety in the ozone standard.

7. *Mortality studies* — No studies have conclusively linked exposure to ozone or photochemical oxidants with an increase in human mortality. A number of epidemiologic studies have been designed and conducted to demonstrate this effect, but in each case the results have been negative or inconclusive.

8. *Welfare effects* — Ozone accelerates the aging of many materials, resulting in rubber cracking, dye fading and paint erosion. These effects are linearly related to the total dose of ozone and can occur at very low levels, given long-duration exposures. Damage to vegetation, as expressed by decreased growth and yield, is related to the long-term (growing season) mean of the daily maximum 6- to 8-hour-average ozone concentrations.

9. *Causes and control of oxidant pollution* — All presently available evidence indicates that around urban centers with severe oxidant problems, the major concern is the formation of photochemical oxidants from man-made organic and nitrogen oxide emissions. Control of these emissions will result in significant reductions in ambient ozone, peroxyacetylnitrate (PAN), aldehydes and photochemical aerosol.

As is the case with most standard-setting activities, the data base on ozone will continue to expand after the standard is set. EPA will continue to inform itself of new research results and also will accelerate the schedule for its own research on the health effects of ozone and other photochemical oxidants at low exposure levels. The Agency plans to make the results of these studies available as they are completed and to issue an interim report on all new research results in two years.

RULEMAKING PETITIONS

The Agency was petitioned by the American Petroleum Institute (API) and 29 member companies on December 9, 1976, and by the City of Houston on July 11, 1977, to revise the criteria, standards and control strategy guidelines for photochemical oxidants. EPA had already begun such a revision when both petitions were filed, and the Agency responded that it was deferring decision on these petitions until the rulemaking was completed. EPA considers this final rulemaking and the accompanying one on control strategy guidelines to be the Agency's final action on these petitions. A summary of the two petitions and EPA's response is given below.

The API petition requested that EPA revise the air quality criteria document for photochemical oxidants in light of new information regarding the causes, effects, and extent of air pollution attributed to ozone and other oxidants. EPA has published a revised air quality criteria document for photochemical oxidants; in the Agency's judgment, this document accurately reflects the latest scientific information regarding the causes, effects, and extent of air pollution attributed to ozone and other oxidants.

The second request in the API petition was that EPA establish a national primary ambient air quality standard based on new studies that allegedly demonstrate no significant adverse human health effects at or below ozone levels of 0.25 ppm for 2-hour exposures. As requested by API and as required under the Clean Air Act, the Agency has considered all new studies published since 1971 that are relevant to setting a revised primary standard the attainment and maintenance of which would, in the Administrator's judgment, protect the public health with an adequate margin of safety. EPA disagrees with API's conclusion that new studies conducted since 1971 demonstrate no significant adverse human-health effects at or below 0.25 ppm.

A more detailed discussion of EPA's judgments regarding reported or probable health consequences at concentrations below 0.25 ppm is presented in the rationale for revising the primary standard and in the response to comments, which appear elsewhere in this notice.

The third request by API was that the national secondary ambient air quality standard be based on adverse effects on public welfare as indicated by studies using ozone-specific measurement methods. In addition, API concluded that Congress intended that EPA weight the overall economic and social impact of a lower secondary standard against adverse effects of a pollutant. EPA has reviewed the data presented in the criteria document and conlcuded that there is currently no evidence of a significant decrease in yield or growth to commercially important crops for short-term exposures to ozone concentrations below 0.12 ppm. EPA believes a secondary standard more stringent than the primary standard is unnecessary and that a cost-benefit analysis is not required.

In their petitions, both API and Houston requested EPA to state the primary and secondary standards so as to permit reliable assessments of compliance. EPA agrees that the present deterministic form of the oxidant standard has several limitations and has made reliable assessment of compliance difficult. The revised ozone air quality standards are stated in a statistical form that will more accurately reflect the air quality problems in various regions of the country and allow more reliable assessment of compliance with the standards.

The API and Houston petitions requested that EPA specify the use of an appropriate measurement method for monitoring ambient concentrations of ozone. API suggested the use of ethylene chemiluminescence calibrated by either gas phase titration (GPT) or ultraviolet (UV) photometry. As a result of EPA's continuing evauation of several calibration techniques, the Agency has defined the reference method to be ethylene chemiluminescence calibrated by UV photometry. (See the amendment to Appendix D of 40 CFR Part 50 elsewhere in this edition of the FEDERAL REGISTER.) EPA is allowing the use of a modified version of the current calibration method (acidified KI) as an interim measure to avoid problems that would result from immediate conversion to UV photometry.

Both the API and Houston petitions requested revision of the State Implementation Plan (SIP) requirements (1) to delete the assumption of no background concentration of photochemical oxidants and (2) to specify more reliable, alternative oxidant prediction relationships to replace Appendix J of 40 CFR Part 51 for determining the degree of necessary precursor emission reductions.

With respect to the first point, EPA recognizes that background concentrations and transport of ozone from upwind locations can contribute to high levels of ozone in or near an urban area during the afternoon hours. Therefore, several revisions are being made in control strategy and implementation guidelines for ozone. The revised guidelines set forth procedures for consideration of both upwind transport and irreducible natural background by the States in calculating the necessary reductions in hydrocarbon emissions. In response to the second request, EPA has determined that Appendix J of 40 CFR Part 51 no longer represents an acceptable analytical relationship between hydrocarbons and ozone. Appendix J is, therefore, being deleted. EPA will now allow States to use any of four analytical techniques to determine the amount of hydrocarbon reduction necessary to demonstrate attainment of the national ozone air quality standards: (1) Photochemical dispersion models, (2) Empirical Kinetics Modeling Approach (EKMA), (3) Empirical and statistical models, and (4) Proportional rollback. These four techniques are discussed further in the revision of Part 51, which appears elsewhere in this edition of the Federal Register.

The Houston petition requested that EPA consider information in their petition relative to atmospheric conditions and other factors that affect photochemical oxidants in the Houston area. The petition claimed that the air pollution problems in Houston warrant special attention in standard-setting and "tailor-made" control strategies, because the emission and meteorology situations and the overall pollution picture in that area are "unique."

In response to the above claim, it should be noted that the majority of the data presented in the revised criteria document are based on ozone exposure. Nearly all of the clinical and toxicological studies are based on the effects of ozone. The biomedical data also suggest that many of the effects observed during periods of elevated photochemical oxidant concentrations are reasonably attributable primarily to ozone in the ambient air. Since the primary and secondary standards are based on the effects of ozone, the differences between areas in their overall photochemical oxidant mixtures do not bear upon the setting of national ozone air quality standards.

EPA agrees with the Houston petition that components of the photochemical oxidant mixture other than ozone may have an adverse impact on health and/or welfare. The data base is not, however, sufficient at this time to justify a separate standard for PAN or other non-ozone oxidants. While EPA does not propose to establish separate standards for the non-ozone constituents of the mixture at this time, those measures taken to reduce ozone precursor emissions will also reduce PAN and other non-ozone oxidant concentration levels.

In response to Houston's request for a unique standard based on their local situation, it must be realized that the Clean Air Act does not contemplate separate standards for different cities. Dealing in terms of *national* ambient air quality standards, the Act charges EPA to identify the air quality levels which must be attained and maintained to ensure, with an adequate margin of safety, that adverse health effects will not occur.

The Houston petition also requested that EPA include realistic requirements for the reduction of oxides of nitrogen as conditions in the Houston area may indicate to be necessary to achieve the revised standards. EPA's response is that it is the responsibility of the State of Texas and the City of Houston to submit State Implementation Plan provisions tailored to the situation prevailing in Houston. If the current SIP is not representative of the most efficient means of reducing ozone in Houston, then, with Houston's assistance, Texas should submit a revision that is consistent with local emission and meteorological conditions.

SUMMARY OF COMMENTS RECEIVED

EPA has solicited public comment and critique on proposed revisions to the photochemical oxidant air quality standard during all phases of the standard development process. Prior to proposal (April 20, 1977), EPA announced (42 FR 20-493) that it was reviewing and updating the criteria document and called for information that might be helpful in revising the document. Public comments were received on two drafts of the criteria document and the public was invited to two meetings of the Subcommittee on Scientific Criteria for Photochemical Oxidants of EPA's Science Advisory Board. In addition, the Agency held a public meeting on January 30, 1978, to receive comments from interested parties prior to development of any formal Agency position on the initial proposed revision of the standard. In particular, EPA actively solicited the participation of the State and Territorial Air Pollution Program Administrators (STAPPA) and the

Association of Local Air Pollution Control Officials (ALAPCO) in this meeting; several representatives of these groups offered comments at the meeting. The results of this meeting are discussed in the proposed regulation (43 FR 26970) and a transcript of the meeting is available in docket OAQPS 78-8.

Following proposal, EPA held four public meetings to receive comments on the proposed standard revisions. Meetings were held in Washington, D.C. — July 18; Atlanta, Ga. — August 17; Dallas, Tex. — August 22; and Los Angeles, Calif. — August 24; transcripts are available in docket OAQPS 78-8. In addition, 168 written comments were received during the formal comment period, which extended through October 16, 1978.

The principal comments and Agency responses are summarized in the following paragraphs (individual responses to comments are contained in docket OAQPS 78-8). EPA also received comments on the proposed standard after October 16. Although EPA does not have a legal obligation to review these comments, all significant issues raised in the post-October 16 comments have been addressed and responded to as part of the discussion of comments in this preamble. As with all other documents considered or examined by EPA as part of its decision process, these documents have been placed in the public docket and have become part of the administrative record of this decision.

The majority of comments received (132 out of 168) opposed EPA's proposed standard revision, favoring either a more relaxed or a more stringent standard. State air pollution control agencies (and STAPPA) generally supported a standard level of 0.12 ppm on the basis of their assessment of an adequate margin of safety. Municipal groups generally supported a standard level of 0.12 ppm or higher, whereas most industrial groups supported a standard level of 0.15 ppm or higher. Environmental groups generally encouraged EPA to retain the 0.08 ppm standard.

Comments on the proposed revisions were received from five Federal agencies. Three of the agencies endorsed the proposed primary standard, but one of these agencies requested that EPA consider formulating the standard on a daily maximum hourly average basis.

Another agency expressed concern that EPA had inadequately substantiated the rationale for raising the primary standard level and requested that the final revisions provide further analysis in this regard. Finally, the Executive Office of the President/Council on Wage and Price Stability suggested, through the Regulatory Analysis Review Group, that the proposed standard was unnecessarily stringent, recommending that EPA set the primary standard using an alternative methodology that focuses on the marginal costs per person-hour of ozone effects avoided.

Groups and individuals submitting comments are identified below:

COMMENTS RECEIVED ENDORSING CURRENT PRIMARY STANDARD LEVEL OF 0.08 PPM

ORGANIZATION AND AGENCIES

American Lung Association of Colorado
American Lung Association of Colorado, West Region
American Lung Association of Louisiana
American Lung Association of New Jersey
American Lung Association of New York State, Inc.
Bangor-Brewer TB and Health Association, Maine
California Lung Association
Connecticut State Department of Health
Environmental Confederation of Southwest Florida
Environmental Defense Fund
Ms. Nancy C. Fahden, Supervisor District Two, Contra Costa County (Calif.) Board of Supervisors
Florida Lung Association
Greenleaf Nurseries, Warsaw, Indiana
Issac Walton League, Manasota Chapter
League of Women Voters of the U.S.
League of Women Voters of Dallas, Texas
Maine Health Systems Agency
Maine Lung Association
Medford-Ashland Air Quality Maintenance Advisory Committee, Oregon
Michigan Lung Association
Michigan Lung Association, Saginaw Valley Region

National Air Conservation Commission, American Lung Association
Natural Resources Advisory Committee, Cedar Grove, N.J.
Natural Resources Defense Council
New Mexico Lung Association
Oregon Environmental Council
Oregon Lung Association
Queensboro Lung Association, Jamaica, N.Y.
Sierra Club
Sierra Club, Houston Chapter
South Shore (Ohio) Christmas Seal Association
Southwestern Ohio Lung Association
U.S. Department of the Interior
Washington Air Quality Coalition
Yale Environmental Law Association

Summary. 35 comments from organizations, agencies or their representatives and 38 comments from concerned citizens supporting the current primary standard level of 0.08 ppm.

COMMENTS RECEIVED ENDORSING PROPOSED PRIMARY STANDARD LEVEL OF 0.10 PPM

ORGANIZATIONS AND AGENCIES

Air Pollution Control League of Greater Cincinnati
Air Quality Advisory Committee, California Department of Health
California Air Resources Board
Coalition of Labor and Business (COLAB), Concord, California
Colorado Department of Health
Connecticut Department of Environmental Protection
Massachusetts Department of Environmental Quality Engineering
Public Health Service, U.S. Department of HEW
Regional Planning Commission for Jefferson, Orleans, St. Bernard and St. Tammany Parishes, Louisiana
Rhode Island Lung Association
Southern Alameda County Board of Realtors, California
U.S. Department of Energy
U.S. Department of Transportation
Wasatch Front Regional Council, Utah
Wayne County Department of Health, Michigan
Wisconsin State Department of Natural Resources

Summary. 16 comments from organizations, agencies or their representatives and 1 comment from a concerned citizen endorsing the proposed primary standard level of 0.10 ppm.

COMMENTS RECEIVED ENDORSING A PRIMARY STANDARD LEVEL OF 0.12 PPM

STATE AND LOCAL AGENCIES

Alabama Air Pollution Control Commission
Berkeley, Charleston, and Dorchester (S.C.) Council of Governments
City of Philadelphia, Pennsylvania
Georgia Department of Natural Resources
Indiana State Board of Health
Kansas Department of Health and Environement
Kentucky Department for Natural Resources and Environmental Protection
Maryland Environmental Health Administration
Michigan Department of Natural Resources
Nebraska Department of Environmental Control
Nevada Department of Conservation and Natural Resources
New York Department of Environmental Conservation
North Carolina Department of Natural Resources and Community Development
Pennsylvania Department of Environmental Resources
Tennessee Department of Public Health
Utah Bureau of Air Quality
Virginia Air Pollution Control Board

ORGANIZATIONS AND COMPANIES

Area Cooperation Committee of Tidewater and Virginia Peninsula Chambers of Commerce
Evansville, Indiana, Chamber of Commerce
Sierra Pacific Power Company
State and Territorial Air Pollution Program Administrators
Texas Oil Marketers Association
Vulcan Materials Company, Wichita, Kansas

Summary. 17 comments from State and local agencies and 6 comments from organizations and corporations supporting a primary standard level of 0.12 ppm.

COMMENTS RECEIVED ENDORSING A PRIMARY STANDARD LEVEL HIGHER THAN 0.12 PPM AND/OR CONTENDING PROPOSED STANDARD TOO STRINGENT

	Endorse standard higher than 0.12 ppm	Proposed standard too stringent
Organization or agency:		
American Petroleum Institute (API)	x	x
Association of Local Air Pollution Control Officials	—	x
Associated Building Industry of Northern California	—	x
Cook County Dept. of Environmental Control, Illinois	—	x
Dow Chemical Company	x	—
Eastman Kodak Company	x	—
General Motors Corporation	x	x
Great Plains Legal Foundation	—	x
Greater San Antonio Chamber of Commerce, Texas	—	x
Houston Chamber of Commerce, Texas	—	x
Iowa-Illinois Gas and Electric Company	—	x
Louisiana Air Control Commission	x	—
Manufacturing Chemists Association	—	x
Monsanto Chemical Intermediates Co.	x	x
Motor Vehicle Manufacturers Association	x	x
National Flexible Packaging Association	x	x
New Orleans Public Service, Inc.	x	—
Oklahoma State Dept. of Health	—	x
Owens-Illinois	x	x
Rio Blanco Oil Shale Company	x	—
St. Louis County, Missouri	x	—
San Antonio Metropolitan Health District, Texas	x	—
Shell Oil Company	—	x
Stearns-Roger, Inc., Denver, Colorado	—	x
Tennessee Eastman Corp.	—	x
Texas Air Control Board	x	—
Texas Chemical Council	x	—
U.S. Council on Wage and Price Stability	—	x
Utah Manufacturers Association	—	x
Virginia Air Pollution Control Board	—	x
Western Oil and Gas Association	—	x
White River Shale Project	—	x

Summary: 15 comments from organizations, agencies, and companies and 4 comments from concerned citizens supporting a primary standard level higher than 0.12 ppm. 23 comments stating the proposed standard is too stringent.

The principal issues raised during the comment period relate to the following topics:

I. Health effect criteria and selection of the primary standard.

A. Definition of an Adverse Health Effect

B. EPA's interpretation of cited studies.

C. Margin of safety.

D. Use of animal studies.

E. Exposure of sensitive groups.

F. Synergistic effects and chemical species designation of the standard.

II. Risk assessment method.

III. Welfare effects and the secondary standard.

IV. Implementation and attainability.

A. Value of hydrocarbon control and timing of SIP submissions.

B. Consideration of control costs.

C. Natural background concentrations.

V. Procedural issues.

The comments received have been reviewed and a document detailing their disposition has been placed in the rulemaking docket (OAQPS 78-8) for public inspection. The following sections summarize the significant comments and present the Agency's responses.

I. HEALTH EFFECT CRITERIA AND SELECTION OF THE PRIMARY STANDARD

A. DEFINITION OF AN ADVERSE HEALTH EFFECT

Comment. The proposed standard is unsuitable because EPA has never defined what constitutes "protection of public health." As a specific example, EPA has not shown that pulmonary function and ventilatory pattern changes are adverse heath effects.

Agency Response. As stated in the criteria document, the available evidence regarding pulmonary function changes observed in clinical exposures of healthy subjects to ozone does not suggest that small changes in lung function (unaccompanied by discomfort symptoms or impairment of oxygen uptake) would interfere with normal activity in healthy individuals. However, even small changes in people with underlying respiratory disease such as asthma, chronic bronchitis, and emphysema can interfere with normal activity and, thus, may signal impairment of public health.

Comment. EPA should identify where adverse effects begin in the continuum of responses to pollutants.

Agency Response. In conducting a preliminary risk assessment, EPA interviewed several biomedical experts to obtain their judgments as to the risk of exceeding the threshold of adverse health effects in sensitive persons for alternative standard levels. An essential feature of this risk assessment procedure is the utilization of the experts' judgments as to the point in the continuum of physiological responses to ozone that must be exceeded for an adverse health effect to occur. As an example, discussions with several experts indicated that a 1 percent decrease in pulmonary function (e.g., forced expiratory volume 1-second test) would be inconsequential, whereas a 50 percent decrease would be a severe effect in sensitive persons; the experts' judgments varied as to the point at which adverse effects would begin, but fell within the range of a 5 to 15 percent decrease.

Comment. Quickly reversible irritation experienced for a short period of time is a welfare effect related to personal comfort and well-being and should therefore be considered in connection with the secondary standard.

Agency Response. The criteria document states that physical discomfort, as manifested by symptoms such as difficulty in breathing, chest tightness, and pain on deep inspiration, has usually been observed in clinical studies in conjunction with pulmonary function changes. Even when reversible, respiratory symptoms may restrict normal activity or limit the performance of tasks. In clinical studies, exposure of *healthy subjects* to realistic levels of ozone (0.3 ppm) has produced discomfort sufficient to prevent completion of experimental protocols, particularly when vigorous exercise was involved. Accordingly the criteria document concluded that increased rates of respiratory symptoms constitute impairment of public health. On this topic, a physician affiliated with the California Department of Health stated (docket OAQPS 78-8, IV-F-31) that it was his medical opinion that symptoms such as those described above constitute adverse health effects, inasmuch as they signal pulmonary function decrements and an increased pulmonary work load for affected individuals. He expressed his concern for the long-term effect of repeated exposure to levels of ozone sufficient to induce such symptoms. EPA concurs in this view and considers such symptoms, even though transitory, to be of concern in selecting the level of the primary standard.

B. EPA'S INTERPRETATION OF CITED STUDIES

1. *DeLucia and Adams (1977)*

Comments. (a) EPA misread the DeLucia and Adams study in claiming significant effects have been reported at 0.15 ppm for one hour.

(b) Mouthpiece breathing may have invalidated the DeLucia and Adams study.

(c) Since DeLucia and Adams demonstrated effects at 0.15 ppm in healthy individuals, more susceptible populations would be expected to sustain effects at lower levels.

Agency Responses. (a) EPA acknowledges that DeLucia and Adams failed to demonstrate any statistically significant decrements in pulmonary function resulting from exposure to 0.15 ppm for one hour. (The investigators did observe statistically significant decrements in pulmonary function resulting from exposure to 0.30 ppm for one hour.) In groups as small as those tested by DeLucia and Adams (six subjects), however, tests of statistical significance are difficult to interpret. The criteria document concluded that the study by DeLucia and Adams, although unreplicated, has raised the question of whether O_3 concentrations as low as 0.15 ppm exert effects in a portion of healthy subjects exercising vigorously. Indeed, DeLucia and Adams specifically state that the two most sensitive subjects sustained markedly impaired respiratory function and exercise ventilatory patterns during the two most stressful exercise protocols in the four ozone-expoure experiments (i.e., both 0.15 ppm and 0.30 ppm).

Furthermore, DeLucia and Adams state that most of the subjects experienced subjective symptoms of discomfort (e.g., congestion, chest pain, and cough) when exposed to 0.15 ppm for one hour under the most stressful exercise protocol (equivalent to running about 6 miles in an hour). These symptoms occurred at a lower exercise rate when the subjects were exposed to 0.30 ppm. DeLucia and Adams did not report the incidence of these symptoms in a quantitative manner, but this fact does not remove EPA's concern about the implications for healthy persons such as those studied by DeLucia and Adams, or for more susceptible persons who may sustain more severe reactions or who may be affected at lower concentrations than those observed.

(b) As noted in the criteria document, persons tend to breathe through their mouths when exercising. Thus, DeLucia and Adams' utilization of mouthpieces to dispense O_3 probably represents actual exposures in persons who, in the course of their normal daily activities, are undergoing exercise.

(c) EPA agrees with this comment, as noted above. EPA considered the implications of this study for more susceptible members of the population in its determination of the margin of safety for the ozone standard.

2. *Schoettlin and Landau (1961)*

Comments. (a) There are still problems with reliance on this study because (1) ambiguities remain in its interpretation and (2) more recent studies of effects of ozone on asthmatics have failed to corroborate this study's conclusions.

(b) EPA's interpretation of the concentration at which Schoettlin and Landau correlated increased incidence of asthmatic attacks is unnecessarily conservative. There is good reason to believe that the 0.25 ppm oxidant concentration cited by Schoettlin and Landau was a daily peak (2-minute average) concentration rather than a daily maximum hourly average concentration, as EPA claims. Furthermore, the level of ozone occurring on these high oxidant days would have been less than the level of oxidant reported.

Agency Responses. (a) The criteria document recognizes limitations that make it difficult to interpret the Schoettlin and Landau study unequivocally. Nevertheless, Schoettlin and Landau did conclude that the proportion of asthmatics having attacks was significantly greater on days when the oxidant concentration exceeded 0.25 ppm than on days when the concentration was below that level. EPA does not believe that this conclusion has been refuted by more recent studies. The reported results of the recent epidemiological study by Kurata et al (1976) are qualitatively similar to those of Schoettlin and Landau. EPA's analysis (docket OAQPS 78-8, IV-A-1) of the data presented in the Kurata study indicates that a statistically significant elevation of the asthma index occurred on days when the maximum instantaneous (2-minute average) oxidant concentrations exceeded 0.28 ppm. While the exact hourly average equivalent of this value is not known, it must be less than or equal to 0.28 ppm, and is probably in the range of 0.20 to 0.27 ppm.

(b) EPA acknowledges that it is uncertain from Schoettlin and Landau's paper what averaging time was used in correlating oxidant concentration and incidence of asthma attacks. As stated in the criteria document, however, consultations with the authors have established that daily asthma attack rates were correlated with daily *maximum hourly average* oxidant levels. EPA considers that these consultations (docket OAQPS 78-8, IIA-C-2) have satisfactorily resolved the controversy regarding the averaging times used by Schoettlin and Landau.

EPA agrees with the comment that ozone levels may have been lower than the oxidant readings with which Schoettlin and Landau correlated asthma attack incidence. Ozone levels have been shown to range from approximately 65 percent to nearly 100 percent of the total oxidant levels. This fact provides reason for concern that ozone in the ambient air at daily maximum hourly average concentrations less than 0.25 ppm may adversely affect asthmatic persons.

3. *Hammer et al (1974)*

Comments. (a) This study has methodological problems (such as the failure to adjust the data for smoking habits and allergy histories) that undermine confidence in its conclusions.

(b) It is uncertain that oxidants caused the increase in symptoms observed in this study.

Agency Responses. (a) Hammer et al. conducted a longitudinal survey of an essentially constant group of subjects over a period of time. Consequently, in order for the authors' failure to adjust the data for smoking habits and allergy histories to have biased the results, the survey response pattern on high pollution days would had to have differed with respect to the distribution of smokers and allergic persons as compared with the pattern on low pollution days. Such an occurrence seems unlikely; furthermore, the criteria document noted that the results of this epidemiological study are generally consistent with the results of clinical exposure studies. This fact, along with the extensive data base evaluated (about 53,000 person-days of observation), enhances the reliability of Hammer's study.

(b) Hammer et al. found that symptom frequencies were more closely correlated to photochemical oxidants than to several other environmental parameters (e.g., carbon monoxide and nitrogen dioxide). In addition, the criteria document noted that the oxidant levels at which cough and chest discomfort were observed to increase in the student nurse population were quite similar to ozone concentrations that have been observed to produce impairment of pulmonary function and respiratory irritation in experimental exposures of healthy subjects performing intermittent light exercise (0.37 ppm for 2 hours). Consequently, it is reasonable to propose that photochemical oxidants — and specifically ozone in the ambient air — contributed substantially to observed increases in rates of cough, chest discomfort, and headache.

4. *Hazucha (1973)*

Comment. Results reported by Hazucha on impairment of pulmonary function at ozone levels of 0.25 ppm for 2 hours are not statistically significant.

Agency Responses. The small number of subjects (three) examined at that exposure precludes the application of statistical methods to the results. The absolute value of the pulmonary function decrements (about 5 percent) is the more relevant factor in evaluating the results of this study.

As described in the criteria document, the small pulmonary function changes observed by Hazucha in a 2-hour exposure of healthy subjects undergoing intermittent light exercise lie along a continuum of responses when compared with results at higher concentrations and similar exposure regimes. There is no indication that 0.25 ppm is the threshold for that exercise level, and indeed the study by DeLucia and Adams (1977) has shown symptomatic effects in *healthy* individuals that are indicative of pulmonary function impariment at levels as low as 0.15 ppm under a more strenuous exercise protocol.

5. *Stuaies in which effects were not observed at levels above 0.15 ppm*

Comments. (a) The 1977 National Academy of Sciences (NAS) document, Ozone and Other Photochemical Oxidants, was cited in several comments as concluding that effects in human subjects have been observed only from ozone exposures above 0.25 ppm.

(b) Linn et al. (1978) failed to find any significant pulmonary effects is asthmatics exposed to 0.20-0.25 ppm for 2 hours under conditions of heat and exercise.

(c) Hackney et al. (1975) observed human health effects only at exposures above 0.25 ppm for 2 hours.

Agency Responses. (a) The NAS document states that "some limited studies show evidence of human health effects of exposure to pure ozone at concentrations as low as 0.25 ppm • • • " This document was prepared before publication of the DeLucia and Adams study, which suggests effects at lower levels. Furthermore, this NAS document in no way concludes that effects resulting from ozone, as it occurs in the ambient photochemical mix, do not occur at concentrations below 0.25 ppm.

(b) Although Linn et al. found statistically significant changes in one of several measures of pulmonary function in their laboratory study, the manner in which the investigators conducted the study (e.g., persons with marked respiratory disability were excluded from the study) and analyzed the data are such that the observed results probably underestimate the effects that would occur at similar ambient exposure levels. There was a slight increase in symptom scores during ozone exposure, and statistically significant changes in blood biochemical factors were observed. While the clinical significance of these latter changes is uncertain, they do represent alterations in normal body functions and cannot be discarded in selecting a standard that protects public health with an adequate margin of safety.

(c) Although the criteria document states that Hackney et al. observed no lung function changes of note at 0.25 ppm for 2 hours even among "reactive" subjects (persons giving a history of cough, chest discomfort, or wheezing in response to allergy or air pollution exposure), closer inspecton of the Hackney et al. (1975) studies reveals that dose-response relationships hold for sensitive subjects for lung function and blood biochemical effects across the range of exposure from 0.20 to 0.50 ppm ozone.

6. *Other Human Studies*

Comments. (a) Von Nieding et al. (1976) have demonstrated effects on pulmonary function of healthy individuals at 0.10 ppm ozone.

(b) EPA cannot justify a conclusion that Japanese epidemiological studies indicate a risk of symptomatic effects in human beings from ozone exposures below 0.15 ppm for one hour.

Agency Responses. (a) EPA is concerned about the findings of von Nieding et al. showing decreased oxygen pressure in arterialized blood and increased airway resistance after 2 hours of exposure to 0.10 ppm ozone and intermittent light exercise. The criteria document points out, however, that the investigators used non-standard physiologic measurement methods. Thus, although von Nieding's findings cannot be ignored in the standard-setting process, they are unconfirmed, and must be interpreted cautiously.

(b) Makino and Mizoguchi (1975) reported an epidemiological study of Tokyo students that showed increased rates of discomfort symptoms on days when the oxidant level (believed to be a daily maximum hourly average concentration) exceeded 0.15 ppm as compared with days when it fell below 0.10 ppm. The criteria document reviewed this and several other Japanese epidemiological studies, and concluded that the studies were appropriately designed but that it is very difficult to interpret their results. In setting a standard with an adequate margin of safety, however, EPA must consider evidence such as these Japanese studies and must evaluate the uncertainties which medical research has not yet resolved.

7. *Validity of Clinical Studies in General*

Comment. At the August 22, 1978 public hearing in Dallas testimony was presented alleging that the ozone generators used in clinical health studies produce other toxic materials in addition to ozone. Experimental data obtained using a new total oxidant monitoring method indicated that these additional oxidants were present in large quantities (as high as 300 percent greater than ozone). It was hypothesized that the adverse effects noted in clinical studies may be preponderantly caused by the additional oxidants and not ozone.

Agency Response. EPA has concluded that the experimental evidence offered to support these findings is unconvincing and cannot be substantiated. The results of an experimental program initiated by EPA after the Dallas hearing indicate that the new monitoring technique which supposedly measured ozone and any additional oxidants has a variable chemical reaction relationship (stoichiometry) with ozone depending on whether or not oxygen is present. The higher oxidant readings obtained by this technique appear to result from this variable stoichiometry rather than representing the presence of any additional non-ozone oxidants. Furthermore, an exhaustive search for such oxidants in the output of ozone generators operating under various conditions (using as the input stream either dry or humidified tank air or oxygen, with very low or background concentrations of hydrocarbons, mostly methane) failed to produce any evidence of non-ozone oxidants. Consequently, EPA judges the hypthesis offered by this comment to be experimentally unsupportable. A report documenting the results of EPA's experimental program has been placed in the docket (OAQPS 78-8, IV-A-2).

C. MARGIN OF SAFETY

Comment. EPA has proposed a standard with an inappropriate margin of safety. The margin of safety was criticized as being either inadequate or too great.

Agency Response. The Clean Air Act requires that EPA set air quality standards that are requisite to protect the public health, allowing an adequate margin of safety. As stated in the legislative history of the Clean Air Act, the standard must protect against hazards that research has not yet identified. EPA feels that the decision regarding an adequate margin of safety is a *judgment* which must be made by the Administrator after weighing *all* the medical evidence bearing on ozone. The factors to be taken into account include inconclusive evidence as well as findings from studies that are considered definitive and not subject to challenge. For example, in selecting an adequate margin of safety, the Administrator must consider: (1) findings from animal studies that show increased susceptibility to infectious respiratory disease and other serious effects at relatively low ozone levels, (2) the concern that health studies may not always reflect the health impact in more sensitive segments of the population, and (3) studies suggesting that ozone may produce an enhanced effect when combined with other air pollutants commonly present in the urban atmosphere but not present in clinical study chambers.

D. USE OF ANIMAL STUDIES

Comment. EPA has failed to give appropriate consideration to the results of animal studies, especially those involving young animals and those examining reduced resistance to infection.

Agency Response. EPA is concerned about the studies which have demonstrated effects in young animals and decreased resistance to infection in animals exposed to ozone. The infection effect has been demonstrated at exposures as low as 0.08 ppm for 3 hours. The criteria document concluded that these findings have definite human health implications, although different exposure levels may be associated with such effects in humans. For this reason, these results cannot be the sole factor used in selecting the level of the primary standard. However, as is the case with other inconclusive evidence, EPA must consider these studies in selecting an adequate margin of safety.

Comment. There is no evidence of reduced resistance to infection in epidemiologic studies in places such as Los Angeles.

Agency Response. Epidemiological studies have been inconclusive in demonstrating this effect in man. However, EPA does not agree with this comment. The study by Durham (1974) of air pollution effects on college students, indicates that rates of new illness increase following short-term exposures to elevated pollutant concentrations. The pollutant variable most strongly associated with illness was peak oxidant. Also, several studies documenting increased levels of mucous membrane irritation during periods of ozone exposure suggest indirectly that susceptibility to infection may rise during these periods. Furthermore, although animal study findings cannot be directy extrapolated to man, the criteria document concludes that the reactions observed in mice represent effects on basic biological responses to infectious agents, and there is no reason to believe that the pollutant-induced alterations of basic defense mechanisms that occur in mice could not occur in human beings. Thus, these studies cannot be ignored in the standard-setting process.

E. EXPOSURE OF SENSITIVE GROUPS

Comment. EPA is being unnecessarily stringent in selecting the sensitive population. The standard could be much less stringent without endangering the health of such persons if EPA accounted for the portion of time that persons are indoors and, thus, not exposed to higher ambient concentrations.

Agency Response. The legislative history of the Clean Air Act makes quite clear Congress' intention to protect sensitive persons (asthmatics and emphysematous patients are cited as examples) who in the normal course of daily activity are exposed to the ambient environment. Air quality standards are to be established with reference to protecting the health of a representative sample of persons comprising the sensitive group rather than a single person in such a group. Standards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment.

F. SYNERGISTIC EFFECTS AND CHEMICAL SPECIES DESIGNATION OF STANDARD

Comment. There were objections to the proposed change of the chemical designation of the standard from photochemical oxidants to ozone because the health impacts of photochemical air pollution arise not only from ozone, but also from the spectrum of other gaseous and particulate pollutants that co-exist with ozone. There was also concern that the change in the chemical designation signalled a change in emphasis in oxidant control efforts that would impede progress in the reduction of non-ozone components of the photochemical oxidant mixture such as peroxyacetylnitrate (PAN). Specific concern was expressed regarding the eye-irritating components of the mixture, since at ambient levels ozone alone is not an eye irritant.

Agency Response. Certain clinical studies (such as Hazucha and Bates, 1975) have demonstrated the potential for greater health impacts resulting from exposure to ozone in combination with other pollutants which occur in the ambient air than from exposure to ozone alone. The ozone standard is not intended merely to protect against the levels of ozone that have been demonstrated to produce effects in clinical studies where subjects have been exposed to highly purified air to which ozone alone has been added. Rather, setting an ozone standard with an adequate margin of safety involves, among other considerations, evaluating the effects of ozone as it occurs in the ambient air, in combination with other pollutants.

One reason for changing the chemical designation of the standard from photochemical oxidants to ozone is to correct an inconsistency between the title of the standard (photochemical oxidants) and the chemical species (ozone) that has aways been measured by the reference method used to estimate ambient oxidant levels and determine compliance with the standard. Consequently, no redirection of control efforts is contemplated; i.e., reductions in hydrocarbon and nitrogen oxide emissions will continue to be required in order to reduce the levels of the secondarily generated pollutant (ozone) measured to determine compliance with the standard.

The criteria document examined the issue of whether or not measures taken to reduce ozone will also reduce other manifestations of photochemical pollution such as eye irritation. The evidence from laboratory and theoretical studies indicates that, for urban atmospheres, reductions in hydrocarbon and nitrogen oxide emissions should have even greater impacts on ambient PAN than on ambient ozone. Similarly, laboratory data suggest a linear relation between hydrocarbon emissions and ambient levels of photochemically produced aldehydes. Since PAN and such aldehydes as fomaldehyde and acrolein are known to be eye irritants, the criteria document concludes that emission control measures for ozone reduction will probably have a positive effect on reducing eye irritation in those situations where eye irritation is associated with photochemical processes (e.g., Los Angeles).

II. Risk Assessment Method

Comment. The risk assessment method should not be used at this time because it has not been reviewed adequately by the Science Advisory Board or the scientific community.

Agency Response. The risk assessment method is not being used to set the ozone standard. In determining what ozone standard has an adequate margin of safety, however, the findings of the initial application of the risk assessment method to ozone have been considered. EPA agrees that the method has not received sufficient review. The method will be published in the open literature and the Science Advisory Board is forming an ad hoc subcommittee to review the method.

Comment. EPA's risk assessment method is incomplete.

Agency Response. EPA agrees with the comment. As applied to ozone, the risk assessment method assesses the risk (probability) that ozone would contribute to health effects in some sensitive people if alternative standards were just met. A complete risk picture would also include information on:

(a) a best point estimate of the number of people affected;

(a') the "expected number" (in a statistical sense) of people affected;

(a'') various risks (probabilities) that the actual number of people affected would be various amounts greater than the expected number;

(b) a best point estimate of the amount of health damage;

(b′) the "expected" health damage; and

(b″) various risks (probabilities) that the actual health damage would be various amounts greater than the expected health damage.

As noted in the draft EPA document explaining the risk assessment method, there are complex technical problems that must be dealt with in responsibly developing information of this type suitable for use in setting National Ambient Air Quality Standards. EPA is presently developing the capability to generate this type of information and will only consider its risk assessment method complete when the method includes this capability.

Comment. The main problem with the risk assessment method stems from its purpose. Instead of estimating health damage, EPA provides a table of risk numbers without providing an estimate of their health significance; these numbers serve no function.

Agency Response. EPA agrees that the risk estimates provided do not serve the function of estimating health damage, but the Agency does not agree that the estimates are without value. The function of these estimates is to indicate the varying risk (or probability) that some sensitive people would suffer health effects in a given period of time if alternative ozone standares were just met. For each health effect category, the response that is of sufficient concern to be deemed a health effect has been decided upon and its seriousness described. As EPA interprets the Clean Air Act, this determination, which is an important step in the process of setting National Ambient Air Quality Standards, is a functon that is to be served by a risk assessment.

There were many comments on both the procedural and the technical aspects of the risk assessment method. EPA will consider these comments in the detailed responses to be placed in the docket. Some of the comments identify improvements that can be made in the risk assessment method, while others reflect misunderstandings that will be dealt with in the detailed docket responses. Some of the comments provide discussion and opinions on various complex issues that arise in the conduct of a program involving the difficult subject areas of risk assessment and standard-setting methodology. EPA will take these comments into advisement as it develops its risk assessment and standard-setting methodologies.

III. WELFARE EFFECTS AND THE SECONDARY STANDARD

Comment. EPA's proposal to retain the existing secondary standard is based entirely on evidence of possible damage to extremely sensitive vegetation. An adequate economic analysis that considers the incremental costs and benefits of alternative secondary standard levels should be conducted. EPA should then weigh the economic costs of pollution control measures against the benefits of reduced damages from lower ozone concentration levels before setting a secondary standard.

Agency Response. The Clean Air Act requires EPA to set a national secondary ambient air quality standard at a level that, in the judgment of the Administrator, is requisite to protect the public welfare from any known or anticipated adverse effects. The term "public welfare," which is defined in Section 302(h) of the Clean Air Act, includes among other things effects on crops, vegetation, wildlife, visibility, and climate, "as well as effects on economic values and on personal comfort and well-being."

EPA has carefully examined the data presented in the criteria document concerning ozone-related damage to vegetation, crops, materials, and visibility. A staff paper, "Evaluation of Alternative Secondary Ozone Air Quality Standards," has been placed in the docket (OAQPS 78-8, IV-A-3).

With regard to damage to materials, the paper concludes that no effect-based rationale can be offered to decide the level of the secondary standard. Damage to materials is linearly related to the total dose sustained by the material. As a result, the annual average concentration will determine the rate at which material damage occurs. Current evidence indicates that annual average concentrations for remote rural areas are comparable to urban areas, due to strong night-time scavenging of ozone in urban areas by man-made pollutants. Reducing the peak 1-hour concentration in urban areas will have virtually no impact on the annual average concentration. Therefore, there would be no measurable reduction in materials damage is a more stringent secondary standard level was selected.

The criteria document states that there is a limited amount of data suggesting an association between ambient ozone and visibility degradation, particularly in the Los Angeles area. On the basis of EPA's evaluation to date of the information presented in the criteria document, however, EPA is unable to conclude at this time that a secondary ozone standard more stringent than the primary standard is necessary to prevent visibility deterioration. The relationship between visibility and ambient ozone will be considered further in the development of subsequent PSD programs designed to protect against significant deterioration of air quality.

Finally, EPA has concluded that there is currently no evidence indicating that a significant decrease in yield or growth of commercially important crops or indigenous vegetation will result from the long-term (growing season) mean of the daily maximum 7-hour-average ozone concentrations which is expected to occur when the primary standard is attained. Consequently, EPA does not believe that a secondary standard more stringent than the primary standard is necessary to protect vegetation from ozone-related yield reduction effects.

On the basis of these conclusions, EPA does not believe that a detailed cost-benefit analysis of alternative standard levels is required, since a secondary standard more stringent than the primary standard is not necessary to protect the public welfare adequately.

Comment. The current secondary standard of 0.08 ppm should be retained to protect vegetation and crops. There is significant reduction in growth and yield to crops exposed to 0.10 ppm of ozone.

Agency Response. The claims that significant reduction in growth and yield occurs in crops as a result of short-term exposures to ozone at levels around 0.10 ppm are undocumented. While sensitive plants may incur foliar injury at low ozone levels, there is currently no evidence that significant yield or growth effects in commerically important crops or indigenous flora are associated with the long-term (growing season) mean of the daily maximum 7-hour-averaging ozone concentrations expected to occur when the primary standard is attained. Consequently, EPA does not believe that a secondary standard more stringent than the primary standard is necessary to prevent ozone-related yield reduction effects in vegetation.

IV. IMPLEMENTATION AND ATTAINABILITY

A. VALUE OF HYDROCARBON CONTROL AND TIMING OF SIP SUBMISSIONS

EPA received comments on the effectiveness of hydrocarbon controls in reducing levels of ozone in the ambient air as well as on the issue of whether or not the statutory deadline for submission of revised State Implementation Plans (SIPs) for nonattainment areas should be postponed because of the changes in the photochemical oxidants standard. The Agency responses to these comments are contained in the accompanying FEDERAL REGISTER notice dealing with the revision of the 40 CFR Part 51 regulations pertaining to the implementation of the standard.

B. CONSIDERATION OF COST CONTROLS

Comment.

Cost of control should be considered in selecting the level of the primary standard.

Agency Response. The Agency's position with respect to control cost consideration was stated in the preamble to the proposed regulation (43 FR 26963); this position remains unchanged. The Clean Air Act specifies that primary National Ambient Air Quality Standards are to be based on scientific criteria relating to the level that should be attained to protect public health adequately. Considerations of cost of achieving these standards or of the existence of technology to bring about needed reductions of emissions are not germane to such a determination, as the words of the Act and its legislative history clearly indicate. EPA has, however, analyzed the cost and economic impacts of the control programs required to attain alternative ozone standard levels in order that the public may be better informed of the consequences of the Agency's decision. This analysis and the comments received in response to it are available to the States for their use in developing strategies to implement the standard.

Comment. The cost estimates presented in EPA's cost and economic impact assessment document are understated.

Agency Response. EPA has carefully reviewed and considered these comments and is publishing a revised economic impact assessment, which is available from Mr. Padgett at the previously mentioned address.

C. NATURAL BACKGROUND CONCENTRATIONS

Several comments were made regarding the contribution of natural sources to ambient ozone concentrations. These comments focus on (1) the extent to which natural background was considered in developing the proposed standards and related control programs and (2) the attainability of these standards, considering the possibility that natural background may at times contravene the proposed levels. Some of the comments suggested that EPA ignored, or did not adequately consider, natural background in developing the proposed standards and related control programs. While this topic was not emphasized in the preamble to the proposed rulemaking, EPA was, and is, cognizant of the background levels that can be attributed to natural sources. This matter was treated extensively in the revised criteria document. Furthermore, EPA procedures for preparation of control plans recommend allowance for natural background in developing control strategies for ozone.

For several years, EPA has been conducting an active field and laboratory research program seeking to determine the nature and extent of background concentrations of ozone. The results of these studies have been widely publicized in EPA reports, scientific literature, and public conferences. One comment suggested that EPA had ignored evidence of natural source impacts reported in contract work conducted for the Agency and that this information had not been released for public review. Actually, all pertinent information available to EPA was considered. However, there may have been some contractualy developed information that had not been released or could not be specifically cited because the contract studies were still in progress and the resulting data had not been fully validated or analyzed. Subsequent to the comment, all information in question were released publically or arrangements have been made to release them as soon as possible.

EPA's review of data related to the background contribution leads the Agency to conclude that such levels are usually well below the proposed levels of the standard, especially during the season of the most active production of photochemical ozone. It is possible, however, that natural events could occasionally cause contravention of the promulgated standard levels. EPA policy (see 40 CRF 51.12(d)) permits data for such occurrences to be disregarded for regulatory purposes. Such events are usually distinguishable because they tend not to coincide with conditions conducive to buildup of man-caused, photochemically produced ozone. Field measurements at some remote sites, where man-caused ozone is likely to be negligible, have shown low — but not insignificant — rates of exceedances of the 0.08-ppm level originally proposed for the secondary standard. The frequencies decrease markedly for concentrations above 0.12 ppm, so that natural exceedances of the standards being promulgated can be considered quite rare at any particular location.

One comment indicated that stratospheric tracer levels measured at surface sites increase by about 40 percent between the front and back side of high pressure systems in the Eastern United States, thus suggesting that stratospheric ozone, through subsidence and horizontal circulation in highs, plays a significant role in the widespread buildup of ozone that tends to occur in the back-side of highs in the Eastern U.S. during the photochemically active season. EPA's estimate is that, even if commonly occurring natural ozone background were increased by 40 percent, the resulting concentration would be insufficient to exceed the standard levels being promulgated. Also, a corresponding increase between the tracer and ozone of stratospheric origin would not be expected, since the tracer is chemically stable near the surface, while ozone is rapidly depleted by reactions with surfaces and with air contaminants.

Some comments referred to a possibly significant contribution to ozone concentrations from reactions involving organic compounds emitted by vegetation. Such emissions are abundant, relative to mad-made emissions, but are relatively diffuse spatially Some of the comments cited a recent statistical study that reported a high correlation between vegetative growth in the Bay Area of California, as indicated by winter rainfall, and the frequency of days with concentrations above 0.08 ppm. EPA has not, however, seen sufficient physical evidence of a relative abundance of natural organics or associated ozone increases in ambient air to consider vegetative sources as significant contributors to high ambient ozone levels. The principal source of natural ozone is still considered to be the stratosphere, with gradual transfer accounting for the more commonly observed background levels, and sporadic intrusions being the principal cause of anomalous high values.

Although research will continue to assess more definitively the contribution of natural sources of ozone, EPA believes that adequate consideration has been given to this issue in developing control programs and implementation guideline documents.

V. PROCEDURAL ISSUES

Comment. EPA's use of an "Advisory Panel on Health Effects of Photochemical Oxidants" was procedurally incorrect in that certain legal requirements on establishment and use of Advisory Committees were not met.

Agency Response. The ad hoc Advisory Panel consisted of a group of medical experts retained by EPA as consultants for the purpose of obtaining their interpretation of the evidence presented in a preliminary version of the criteria document. As such, EPA did not regard the Panel as an advisory body within the meaning of the Advisory Committee Act of 1972. In any case, the Panel's report has been in the docket and subject to comment since proposal, and bases for its recommendations have been fully aired.

Comment. In revising its criteria document, EPA failed to comply with the recommendations of the statutory scientific review body, the Science Advisory Board (SAB), as evidenced by the SAB's refusal to approve the criteria document.

Agency Response. The function of the Science Advisory Board subcommittee is to advise EPA regarding the scientific and technical accuracy, the manner of presentation, and the adequacy of the criteria document. Inevitably, no two scientists ever agree completely on the importance, accuracy and manner of presentation of data. In the final analysis the responsibility for the criteria document rests with EPA and, therefore, the decision regarding the content of the document must also rest with EPA.

EPA solicits the advice of its scientific advisors and has attempted to respond to the specific comments made by members of the SAB subcommittee established to review the criteria document by incorporating suggested changes in the document. Following the last SAB subcommittee meeting in February 1978, members of the subcommittee who had specific comments were consulted by EPA personnel, and their comments and criticisms were discussed with them prior to making the changes in the document. It has always been Agency policy that once the EPA staff had considered the changes suggested by the SAB and, where appropriate, incorporated them into the criteria document, the Agency would proceed with publication. Consequently, EPA feels that the criteria document adequately reflects the latest scientific knowledge pertaining to the effects of ozone and other photochemical oxidants.

Comment. EPA has failed to submit the proposed standard to the SAB for review as required by the Environmental Research, Development, and Demonstration Authorization Act of 1978 (Pub. L. 95-155). EPA should do so before promulgating the standard.

Agency Response. The development of the ozone standard revision, which began in 1976, followed the procedural process in place before the enactment of Public Law 95-155. Accordingly, the SAB was asked to review only the criteria document. The independent committee established in accordance with the 1978 Act held its first session in October 1978, when there was not adequate time for it to review the standard. The thorough review of the technical and scientific basis for the criteria document, which is in turn the basis for the standard, substantially complies with the objectives of the Act.

SELECTING THE LEVEL OF THE PRIMARY STANDARD

EPA's objective in setting the standard level is to select an ozone concentration that will reflect an accurate consideration of the existing medical evidence and an adequate assessment of the uncertainties in this evidence, and, thus, will protect all population groups with an adequate margin of safety.

The criteria document supports the contention that a clear threshold of adverse health effects cannot be identified with certainty for ozone. Rather, there is a continuum consisting of ozone levels at which health effects are certain, through levels at which scientists can ally agree that health effects have been clearly demonstrated, and down to levels at which the indications of health effects are less certain and harder to identify. Given such a body of evidence, in selecting a standard with an adequate margin of safety the decision-maker is taking into account the uncertainty about whether a possible standard will prevent adverse health effects.

This uncertainty results from several factors. First, human susceptibility to health effects varies, and we cannot be certain that experimental evidence has accounted for the full range of susceptibility. Second, we cannot be certain that all effects occurring at low ozone levels have been identified and demonstrated. Third, variations in weather create uncertainty as to the expected annual maximum ozone concentrations.

The Clean Air Act, as the Administrator interprets it, does not permit him to take factors such as cost or attainability into account in setting the standard; it is to be a standard that will adequately protect public health. He recognizes that controlling ozone to very low levels is a task that will have significant impact on economic and social activities. This recognition causes him to reject as an option the setting of a zero-level standard as an expedient way of protecting public health without having to decide among uncertainties. However, it is public health, and not economic impact, that must be the compelling factor in the decision. Thus, the decision as to what standard protects public health with an adequate margin of safety is based on the uncertainty that any given level is low enough to prevent health effects, and on the relative acceptability of various degrees of uncertainty, given the seriousness of the effects.

In selecting the proper level for the standard, EPA must make assessments and judgments in five critical areas:

1. Reported effect levels from human studies.

2. Characterizing the sensitive population.

3. Nature and severity of effects.

4. Probable adverse heath effect level in sensitive persons.

5. Judgment of a standard level below the probable effect level that provides an adequate margin of safety.

Reported Effect Levels

In the preamble to the proposed standard (43 FR 26965), EPA presented a table of demonstrated effect levels in man ranging from 0.15 to 0.30 ppm. On the basis of suggestions received during the comment period, that table has been expanded to include a greater number of studies where effects have been reported. EPA believes that this is a more complete representation of the medical evidence since it includes some less conclusive studies at low levels that cannot be discarded in weighing the full body of health data. Nonetheless, the table must be used with caution and in conjuncton with qualifying statements made in the criteria document regarding the technical merit of each study, particularly the less conclusive studies at lower concentrations.

While this table does not provide an undisputed value for adverse health effect levels in sensitive individuals, it does indicate that normal body functions are most likely disrupted at relatively low ozone concentrations. The studies also indicate that the intensity and significance of effects increases as the pollutant level increases. The reported findings leave open the question of increased intensity of effects in more sensitive persons and the concern that effects reported in some studies may occur at lower concentrations when ozone is present in combination with other urban pollutants.

Sensitive Population

The legislative history of the Clean Air Act indicates that, in setting primary ambient air quality standards, EPA is to direct its efforts at groups of "particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." (U.S. Senate Serial No. 93-18, 93d Cong. 2d Sess. p. 410).

Clinical and epidemiological studies have shown that persons with chronic obstructive airway disease, particularly asthmatics, appear

REPORTED EFFECT LEVELS

Compilation of Results Reported in Human Studies Examining Ozone or Oxident Exposure

Concentration, ppm	Exposure Duration, hours (for clinical studies); Averaging time (for epidemiological studies)	Pollutant Measured (O_3 = ozone, O_x = oxidant)	Reported Effect(s)	Reference(s)
0.01 0.30	hourly average	O_3	Lung function parameters in about 25% of Japanese school children tested were significantly correlated with O_3 concentrations (over the range of 0.01 - 0.30 ppm) in the 2 hours prior to testing.	Kagawa and Toyama (1975); Kagawa et al. (1976)
0.03 0.30	hourly average	O_x	Although significant correlation was observed between decreased athletic performance and O_x concentrations in the range of 0.03 - 0.30 ppm, the criteria document states that inspection of the data reveals no obvious relationship between performance and O_x values below 0.10-0.15 ppm.	Wayne et al. (1967)
0.10	2	O_3	Decreased O_2 pressure in arterialized blood, increased airway resistance observed using non-standard measurement techniques.	von Nieding et al. (1976)
0.10 0.15	probably daily maximum hourly average	O_x	Increased rates of respiratory symptoms and headache were reported by Japanese students on days when O_x concentrations exceeded 0.15 ppm as compared to days when O_x concentrations were less than 0.10 ppm.	Makino and Mizoguchi (1975)
0.15	1	O_3	Subjective symptoms of discomfort were observed by most subjects, and discernible but not statistically significant changes in respiratory patterns occurred while performing vigorous exercise.	DeLucia & Adams (1977)
0.20	3	O_3	Reduction in visual acuity (night vision) observed.	Lagerwerff (1963)
0.20 0.25	2	O_3	Asthmatic patients exposed under intermittent light exercise conditions showed no statistically significant changes in respiratory function. Symptom scores increased slightly during O_3 exposures. Small but statistically significant blood biochemical changes occurred.	Linn et al. (1978)
0.25	2	O_3	Small changes in lung function were observed in 3 subjects performing intermittent light exercise.	Hazucha (1973)
0.25	2 and 4	O_3	No lung function changes of note were observed in "reactive" subjects (who had histories of cough, chest discomfort or wheezing associated with air pollution or allergy) while performing intermittent, light exercise.	Hackney et al. (1975)
0.25	daily maximum hourly average	O_x	The average number of asthma patients having attacks was statistically significantly elevated on days when O_x levels exceeded 0.25 ppm.	Schoettlin and Landau (1961)
0.25	0.5 - 1	O_3	Blood samples of exposed subjects had increased rates of sphering of red blood cells	Brinkman et al. (1964)
0.28	daily maximum instantaneous (2-minute) average	O_x	Although the reported results are inconclusive, EPA's examination of the evidence presented suggests exacerbation of asthma when O_x levels are above 0.28 ppm.	Kurata et al. (1976)
0.30	1	O_3	Subjective symptoms of discomfort and statistically significant changes in pulmonary function were observed in subjects undergoing vigorous exercise.	DeLucia and Adams (1977)
0.30	daily maximum hourly average	O_x	Increased rates of cough, chest discomfort, and headache were observed in student nurses on days when the O_x concentrations exceeded 0.30 ppm.	Hammer et al. (1974)
0.37	2	O_3	Discomfort symptoms and significant changes in lung function were observed in subjects undergoing intermittent light exercise.	Hazucha et al. (1973); Folinsbee et al. (1975); Silverman et al. (1976)
0.37 0.37	2 2	O_3 SO_2	Exposure to O_3 and SO_2 together produced changes in lung function substantially greater than the sum of the separate effects of the individual pollutants.	Hazucha and Bates (1975)
0.37 0.37	2 2	O_3 SO_2	The observed O_3 - SO_2 interactive effect on lung function was considerably smaller than that seen by Hazucha and Bates. The authors concluded that the earlier study probably more nearly simulated a smog episode in regions having high oxidant and sulfur pollution.	Bell et al. (1977)

most sensitive to changes in ozone concentrations. This sensitivity results from the fact that their airways are hyper-reactive to irritants such as ozone. These people are, thus, judged to be the principal sensitive group of concern in setting the standard.

Studies have also established that exercise effectively increases the ozone dose delivered to the target tissues in the respiratory tract. Thus, persons engaging in exercise are particularly vulnerable to the acutely irritating effects of ozone. The response of these groups to such changes in concentrations has not, however, been systematically studied.

NATURE AND SEVERITY OF EFFECTS

Impaired Pulmonary Function and Clinical Sypmtoms — Ozone is a pulmonary irritant that affects the mucous lining, other lung tissue, and respiratory function. Changes in lung function appear as increased airway resistance and as reductions in vital capacity, expiratory flow rates, and diffusion capacity. These effects are greater in exercising individuals and individuals with hyper-reactive airways (i.e., individuals with a history of developing symptoms during light activity in smog or history of asthma). Changes in lung function are accompanied by clinical symptoms such as coughing, chest tightness, and lower chest soreness.

Because the human respiratory system is endowed with a large reserve, even airway-resistance increases of 50 to 100 percent will not ordinarily be perceived in normal individuals. As stated in the criteria document, however, two considerations suggest that oxidant-associated changes in lung function may signal impairment of public health. First, in people with underlying respiratory illness such as asthma, chornic bronchitis, and emphysema, even small decrements in lung function often interfere with normal activity. Second, at experimental ozone concentrations as low as 0.30 ppm, decrements in lung function have usually been accompanied by physical discomfort, as manifested in symptoms such as sore throat, chest pain, cough, and headache. At times this discomfort has been great enough to prevent the completion of experimental protocols, particularly when subjects have been execising vigorously. It appears quite likely that the pulmonary irritant properties of ozone (and perhaps other oxidants) underlie both the discomfort and the decrements in function. Thus, at least when associated with ozone exposure, changes in lung function often represent a level of discomfort which, even among healthy people, may restrict normal activity or impair the performance of tasks.

Decreased Resistance to Infection — This effect is represented by an increased rate of mortality in laboratory animals subjected to both a bacterial challenge and exposures to ozone. According to some studies, the effect may be enhanced by the addition of such stresses as exercise or the addition of other polutants in combination with the ozone dose. Despite the uncertainties involved in predicting human effects from animal studies, medical experts agree that decreased resistance to infection probably does occur in man. The Durham study (1974) reporting increased illness in college students following periods of elevated pollution levels (with peak oxidant being the pollution variable most strongly associated with illness) reinforces this hypothesis and adds to EPA's concern about the relationship of ozone to the occurrence of such an effect in man.

Aggravation of Chronic Respiratory Disease — Although the relationship between ambient oxidant or ozone levels and chronic pulmonary disease has not been fully assessed, available evidence suggests that the incidence and severity of asthma attacks increase when short-term total oxidant concentrations exceed 0.25 to 0.28 ppm. Also, several investigators have reported a relationship between short-term oxidant exposure and aggravation of other chronic obstructive lung diseases. However, their reports are inconclusive since the short-term fluctuations in cigarrette smoking habits were not considered in their data analyses.

Air pollution is one of the many stresses that can precipitate an asthma attack or worsen the disease state in persons with chronic cardio-pulmonary disease. Other factors that can precipitate attacks include respiratory infections, passage of cold fronts, seasonal pollens, extreme heat or cold, and emotional disturbances.

Eye Irritation — Eye irritation is associated with selected chemical species (such as PAN) in the photochemical oxidant mix and with other organic vapors. While there is no evidence that eye irritation is produced by ozone, an ozone standard will serve to limit this effect because control measures that reduce ozone will also reduce the eye-irritating components in the total oxidant mix.

Biochemical Effects — Experimental exposures of human subjects to ozone have produced changes in blood biochemistry, such as increased fragility of red blood cells and altered enzyme activities in the serum. The significance of these ozone-mediated changes is not yet known, but the criteria document states that changes of the magnitude observed in human experimental exposures have not yet been linked to any clinical diseases.

Carcinogenic, Mutagenic and Related Effects — Studies have been conducted in an attempt to relate ozone to carcinogenic, mutagenic, and related effects. Available evidence in these areas is not particularly helpful in setting ambient ozone standards because most of the studies have not yet been replicated (in spite of some attempts to do so), and because some effects observed in lower life forms are of questionable significance for man. The criteria document states that the significance of effects such as chromosomal aberrations has not been established and that some studies have produced conflicting results. In addition, EPA's Science Advisory Board recommended that certain studies on the mutagenic effects of ozone, which have not been replicated, not be emphasized in the criteria document.

PRIMARY STANDARD

As illustrated in the table of reported effect levels, there is no clear threshold air concentration of ozone indicated by the data as the onset of adverse health effects. It is EPA's best judgment that physiological responses probably occur in extremely sensitive persons at very low levels. At what point these responses become an adverse health effect and at what level they most likely occur in sensitive persons must necessarily be an informed judgment. As stated in the proposal, this judgment is based on (1) the Agency's understanding of the medical evidence presented in the criteria document and in the table of reported effect levels, (2) the findings of the advisory panel on health effects, and (3) the judgment of medical experts as to the adverse effect level in sensitive persons. The health experts who were consulted were asked to focus not only on the most sensitive population

PROBABLE EFFECT LEVEL ESTIMATES
(Estimates for Sensitive Population Segments)

	Aggravation of asthma, emphysema, and chronic bronchitis	Reduced resistance to bacterial infection (animal studies)	Reduction in pulmonary function	Chest discomfort and irritation of the respiratory tract
Health panel judgment of effect level	0.15-0.25	Not available	0.15-0.25 ppm	0.15-0.25 ppm
Probable or median effect level as estimated from interviews with health experts (Range of estimates given in parentheses)	0.17 ppm (0.14-0.25 ppm)	0.18 ppm (0.07-0.38 ppm)	0.15 ppm (0.07-0.18 ppm)	0.15 ppm (0.11-0.18 ppm)

group, but also on a very sensitive portion of that group (specifically, those persons who are more sensitive than 99 percent of the sensitive group, but less sensitive that 1 percent of that group). The lowest adverse health effect level estimate cited by the health panel and the median values developed through the expert interview process are reasonably consistent, ranging from 0.15 to 0.18 ppm (See table below.) On the basis of the effect levels cited in the criteria document, it is EPA's judgment that the most probable level for adverse health effects in sensitive persons, as well as in healthier (less sensitive) persons who are exercising vigorously, falls in the range of 0.15-0.25 ppm. While the evidence is more convincing and the effects more pronounced at the higher end of this range, the data shows effects of concern at the lower concentration.

In order to set an ambient air quality standard that protects the public health with an adequate margin of safety, EPA must deal with the uncertainty inherent in the judgment that the probable level for adverse effects in sensitive persons is in the range of 0.15-0.25 ppm.

Because the nature and intensity of effects vary from pollutant to pollutant and because medical research produces new and different findings as science progresses, EPA does not believe that a fixed acceptable margin of safety can be established for all pollutants or for a single pollutant over time. Each decision on a standard level must be made on the best evidence available at the time and should include consideration of such factors as:

1. *Concern for more sensitive individuals* — Sensitive persons may respond to ozone differently from the less sensitive persons who generally are tested in clinical studies. Individuals with underlying respiratory illness such as asthma, chronic bronchitis, and emphysema are particularly sensitive to even modest impairments of pulmonary function resulting from ozone exposure. For ethical reasons, clinical investigators normally do not expose persons with these illnesses and thus caution that such studies may not represent the full range of sensitivity to ozone. Also of concern are individuals engaged in vigorous outdoor activity (construction work, tennis, jogging, etc.) where the effects of ozone are enhanced or may occur at lower ambient concentrations.

2. *Pollutant interactions* — There is real concern that effects reported in some ozone studies may occur at lower concentrations and may be enhanced when ozone is present in combination with other urban pollutants. Laboratory studies of a single pollutant (e.g., ozone in clean, filtered air), while important in elucidating physiological effects peculiar to that pollutant, cannot be viewed as providing definitive evidence of the minimum level at which these effects occur when that pollutant is present as only a part of the total insult delivered to an individual in the urban environment. Also of concern are other toxic oxidant species, such as PAN, that are often present with ozone in the ambient photochemical pollution mixture and cause other adverse effects such as eye irritation. Thus, the effects of ozone must be considered in the context of the total environment of the exposed individual; this environment includes concentrations of other pollutants consistent with their maximum allowable levels, high relative humidity, high ambient temperature, and high levels of physical stress.

3. *Long-term deleterious effects of ozone* — Unfortunately, there are few studies that have attempted to document the long-term adverse effect of human exposure to repeated peaks of ozone. Some animal studies do indicate that long-term ozone exposures act as an inducer of biochemical or morphological changes. Some of these changes are transient and, on a short-term basis, may have a physiological significance in that they confer a resistance against further lung injury in an oxidant environment (a similar response has been observed in human clinical studies). Some animal studies have indicated, however, that effects from continued exposure can result in an emphysema-like condition (e.g., P'an et al., 1972).

4. *Animal infectivity studies* — Although evidence of reduced resistance to bacterial infection has not reached the point were it can be meaningfully used to extrapolate concentrations that would similarly affect man, these studies cannot be dismissed in selecting a standard level that provides an adequate margin of safety. Despite the present inability to extrapolate to an effect level in humans, most experts agree that ozone exposures may well result in decreased resistance to infection in humans. Further, it is the kind of effect that is serious enough in its implications to raise a need for caution. Thus,

it is prudent public health practice to set a standard more stringent than the probable effect level estimated from the human studies, in order to account in some measure for these unquanitified, but possibly serious, effects.

5. *Inconclusive studies reporting effects at low levels* — A similar caution is suggested by both the Makino and Mizoguchi epidemiological study and the von Nieding clinical study reporting effects at levels around 0.10 ppm.

6. *Uncertainties arising from air quality variations due to meteorology* — Since EPA's revised standard is statistically based and permits an expected number of allowable violations per year, there is concern about the magnitude of these excursions and how they might impact an exposed sensitive individual.

7. *Effects of calibration procedure change* — Another factor that has been considered in establishing a margin of safety is the variability that exists in the measurements and calibration techniques used in health studies and how these measurements may differ from those made with the ultraviolet (UV) reference calibration procedure being promulgated elsewhere in this issue of the FEDERAL REGISTER. Most of the relevant clinical studies utilized monitoring instruments calibrated with the current (NBKI colorimetric) reference calibration procedure or modifications thereof. EPA's best judgment is that the reference NBKI procedure shows a positive bias of about 10 percent with respect to the UV procedure when these techniques are compared under carefully controlled experimental conditions. However, due to the variability that can reasonably be expected in any clinical exposure monitoring measurements, as well as the uncertainty introduced by the modified calibrations procedures, EPA cannot determine a precise quantitative factor to adjust the findings of these health studies. In the case of the study done by DeLucia and Adams (1977), the authors have indicated to EPA that the reported ozone values might be high with resepct to the UV calibration procedure. While the exact magnitude of any required adjustment in the reported ozone values is uncertain, adjusted values could range from 0.12 to 0.15 ppm for the 0.15 ppm value reported by the authors, and from 0.23 to 0.30 ppm for the 0.30 ppm concentration. EPA will continue its evaluation of this issue through its program of clinical exposure studies.

8. *Findings from the preliminary risk assessment* — The preamble to the proposed standard described a preliminary risk assessment method performed to aid EPA in accurately treating the uncertainties associated with a standard decision. While this method cannot be used at this time as the sole tool for making that decision, the Agency does believe that the findings resulted from this initial application of the method do not permit any relaxation of the standard above 0.12 ppm.

After reveiwing the comments received from all segments of the public, including those from the public health community, EPA remains convinced that at levels in the range of 0.15-0.25 ppm, adverse health effects will almost certainly be experienced by significant numbers of sensitive persons. Unless the standard is set somewhat below that level, the Agency would not be exercising that degree of prudence called for by the "adequate margin of safety" requirement of the Clean Air Act. The Administrator must exercise the informed scientific judgment that Congress has authorized him to bring to bear on these difficult problems.

There is no collection of facts or medical evidence that permits selecting an undisputed value for the standard level. EPA proposed a standard of 0.10 ppm, taking several factors into account in providing a margin of safety, as discussed above. Among those were epidemiological studies indicating effects below 0.15 ppm which the criteria document did not fully endorse, but which EPA thought it unwise to disregard (See 43 FR 26966.) Also considered were animal studies indicating reduced resistance to bacterial infection, although extrapolation to human effects levels is not possible. *(Id.)* During the comment periods, EPA received informed scientific opinion disputing the interpretation and application of such studies. Based on its current understanding of these studies, EPA has concluded that they do not dictate as wide a margin of safety as was established in the proposal. EPA does believe, however, that these studies do suggest the real possibility of significant human adverse health effects below 0.15 ppm. Consequently, the Administrator had determined that a standard of 0.12 ppm is necessary and is sufficiently prudent unless and until further studies demonstrate reason to doubt that it adequately protects public health.

WELFARE EFFECTS AND THE SECONDARY STANDARD

The Clean Air Act mandates the setting of a national secondary ambient air quality standard to protect the public welfare from any known or anticipated adverse effects associated with an air pollutant in the ambient air. Ozone and other photochemical oxidants constitute a form of air pollution that has been shown to affect vegetation and materials and that may have an impact on visibility. The economic loss resulting from current oxidant levels has been estimated to be in the range of several hundred million dollars per year nationwide. Non-quantifiable losses to the natural environment occur as well. A staff paper, "Assessment of Welfare Effects and the Secondary Air Quality Standard for Ozone," was placed in the docket at the time of proposal. The following paragraphs summarize this report and information received after its release.

Exposure of vegetation to harmful levels of ozone may result in leaf injury, decreased growth and yield, or reproductive effects. Visible leaf injury is the most readily detectable and frequently reported symptom of ozone damage; however, it is not an accurate indicator of yield or growth reduction.

In the June 22, 1978, FEDERAL REGISTER proposal (43 FR 26968-26969), it was stated that several investigators suggested that foliar injury rates in the range of 5 to 10 percent could produce detectable reductions in growth or yield, depending on the timing of the injury and other environmental factors. Since proposal of the standard in June, EPA has discussed the matter further with several experts in the field of air pollution damage to vegetation, particularly regarding what level of leaf injury should be of concern in protecting against significant reductions in yield or growth in commercially important crops and indigenous flora. These experts emphasized the uncertainty associated with correlating yield reduction with foliar injury. Some stated that detectable yield reductions would not occur until leaf injury reached values as high as 10 to 20 percent, and others felt that foliar injury was an inappropriate indicator of yield reduction.

The foliar responses of plants to ozone exposures are not linearly dependent on the dose (product of concentration and exposure duration) sustained by the plant. A given dose applied over a short period of time is more damaging than if it were applied over a longer period. EPA used a mathematical model to summarize, for several crops, the experimental results which depict the variation in foliar response with short-term (0.5-hour to 8-hour) ozone exposures. The notice of proposed rulemaking predicted (on the basis of the mathematical model) that a secondary ozone air quality standard set at an hourly average conentration of 0.08 ppm, expected to be exceeded only once per year, would prevent any important commercial crop from receiving more than 3 percent leaf injury. On the basis of this prediction and the aforementioned assumptions regarding the relationship of foliar injury and yield reduction, EPA proposed to set the secondary standard level at 0.08 ppm.

As a result of its further consultations with researchers, EPA decided to reassess the uncertainties associated with the judgments that led to the proposed 0.08 ppm 1-hour average secondary standard. These experts pointed out that there are large uncertainties in the assumptions relating yield reduction to foliar injury. The mathematical model used to predict foliar injury was based on chamber studies, not on studies conducted under field conditions. The experts cautioned that these chamber studies generally represent experimental conditions in which the most sensitive varieties of a given species are used and in which moisture and temperature are optimal for producing injury. In addition, a given short-term does of ozone, which can produce 5, 10, or even 20 percent foliar injury in a given plant, is unlikely to have an impact on yield unless the plant is exposed during a critical stage in the plant's life cycle.

Consequently, EPA has decided to base its decision on the secondary ozone air quality standard on the information currently available on growth and yield reduction in commercially important crops and indigenous vegetation exposed to ozone under field conditions. As discussed in a staff paper that has been placed in the docket (OAQPS 78-8, IV-A-3), "Evaluation of Alternative Secondary Ozone Air Quality Standards," these data indicate that growth and yield responses are related to the long-term (growing season) mean of the daily maximum 6- to 8-hour-average ozone concnetrations. Based on an examination of this information, and the available air quality data, EPA concludes that there is currently no evidence indicating that a significant decrease in growth or yield of commercially important crops or indigenous flora will result from the long-term mean of the daily maximum 7-hour-average ozone concentrations expected to occur when the primary standard is attained. Consequently, EPA believes that a secondary standard more stringent than the primary standard is not necessary on the basis of ozone-related yield reduction effects in vegetation.

Materials damage resulting from ozone can be described as an acceleration of aging processes; for example, rubber cracking, dye fading, and paint weathering. In contrast to the effects of ozone on vegetation, these effects are linearly dependent on the total ozone dose sustained by the material. As a result, the annual average concentration will determine the rate at which material is damaged. Any non-zero ozone concentration (including natural background levels) will contribute to the deterioration of sensitive materials over a sufficient exposure duration. While peak 1-hour ozone concentrations in urban areas tend to be considerably higher than in rural areas remote from man-made emission sources, the annual average concentrations observed in these areas are essentially the same. This finding is believed to be due to the impact of very low urban-area nighttime ozone concentrations on the annual average values; nighttime ozone levels in remote areas are not reduced as much from the daytime levels due to the absence of scavenging by man-made urban pollutants. As peak ozone levels in urban areas are reduced through control of man-made pollutants, scavenging will also be reduced resulting in little if any change in the annual average. Consequently, no effect-based rationale can be offered to decide the level of the secondary standard needed to protect materials. Accordingly, EPA believes that a secondary standard more stringent than the primary standard is not necessary on the basis of ozone damage to materials.

The criteria document states that there is a limited amount of data suggesting an association between ambient ozone and visibility degradation, particularly in the Los Angeles area. On the basis of EPA's evaluation to date of the information presented in the criteria document, however, EPA is unable to conclude at this time that a secondary ozone standard more stringent than the primary standard is necessary to prevent visibility deterioration. The relationship between visibility and ambient ozone will be considered further in the development of subsequent PSD programs designed to protect against significant deterioration of air quality.

On the basis of these conclusions with respect to ozone damage to vegetation and materials and the association of ozone with visibility reduction in some areas, EPA is revising the secondary ozone air quality standard level to 0.12 ppm.

OTHER ASPECTS OF THE STANDARD

On the basis of EPA's evaluation of evidence submitted and comments received during the public review process, no major changes will be made in the following aspects of the proposed standard: (1) Averaging time: 1 hour; (2) chemical species: ozone; (3) form: statistical; and (4) a separate standard for PAN is not being promulgated. As discussed below, changes will be made in (1) the set of hourly averages from which the number of exceedances of the standard level is counted, and (2) the exclusion criteria for missing data.

DAILY MAXIMUM HOURLY AVERAGE INTERPRETATION OF THE STANDARD

The maximum ozone concentrations which will occur in any given time period will vary from one period to the next, even if precursor emissions remain constant. These variations are mainly due to the random nature of meteorological factors which affect the formation and dispersion of ozone in the atmosphere. The present deterministic form of the standard, which permits only a single hourly exceedance of the standard level in any year, inadequately deals with this situation. The risk to public health contributed to by ozone can be managed better if the ozone standard reflects the fact that maximum ozone concentrations are probabilistic in nature. Consequently, EPA is changing the standard to a statistical form that allows one expected exceedance per year.

The proposed standard would have allowed one expected hourly exceedance per year. EPA is further modifying the standard so that the one expected exceedance will be given a daily interpretation; that is, a calendar day will exceed the standard level if the maximum hourly average concentration for the day exceeds the level of the standard. This modification means that a day with two hourly values over the standard level counts as one exceedance of the standard level rather than two; similarly for days with more than two hourly values over the standard level. As was indicated in the proposal notice, the daily interpretation has some advantages and it is evident from the comments received that there is considerable support for the use of this interpretation.

It should be understood that the change to a daily interpretation is not predicated on a reinterpretation of health data. In making this change, EPA is not concluding that 3 hours of exposure above a given level, for example, are no worse than 1 hour of exposure above the same level as long as the 3 hours of exposure occur during the same day. The impact of ozone is related to the total dose delivered to the respiratory tract, and obviously for a given concentration a 3-hour exposure gives a greater dose than a 1-hour exposure. In the case of ozone, the pattern of hourly levels is mainly determined by meteorological fluctuations, and EPA's decision to promulgate a daily standard does not affect meteorological fluctuations. Ozone precursor emissions are not easily manipulated on a short-term basis, so there is little likelihood that emission sources could readily alter emission patterns to take advantage of the daily interpretation.

The change to a daily interpretation does make the standard slightly less stringent, and hence there is a small increase in the risk to health. In general, the reduction in emissions of organic compounds needed to meet the standard under the daily interpretation will be smaller. As discussed in a report placed in the docket (OAQPS 78-8, IV-A-4), the long-term increase in health risk at an average geographical location is estimated to be equivalent to the increase that would result from raising the level of the standard to 0.123 ppm and keeping the hourly interpretation of the number of exceedances.

EXLCUSION CRITERIA FOR MISSION DATA

EPA is additionally modifying the standard with respect to the treatment of missing data. The proposed standard permitted certain missing values to be excluded from the estimated exceedances calculation if either of two exclusion criteria were satisfied. The first criterion recognized the impact of short-term meteorological influences by allowing a missing value to be excluded if the adjacent values were below an arbitrary limit (75 percent of the standard level). This criterion should be relatively easy to incorporate into data-handling schemes and has been retained, although it now applies to daily maximum hourly average values. The second criterion dealt with comparisons with data from the previous 3 years. The purpose of this second criterion was to accommodate situations for which ozone data for a particular season are not available but for which known seasonal patterns of ozone and related meteorological factors make it unlikely that the level of the standard would have been exceeded.

This second criterion would be more difficult to implement because it necessitates the cross-referencing of eariler historical data. For newly established monitors, the historical data needed to invoke this exclusion would not be available. Thus, this second criterion in the proposal is difficult to implement and could be potentially burdensome in geographic areas where the climate makes high ozone values during certain seasons very unlikely. It is also possible to accomplish the intended purpose of this exclusion through provisions of the recently proposed 40 CFR Part 58 (see 43 FR 34892) that would grant waivers of the ozone monitoring requirements for certain times of the year at the discretion of the appropriate Regional Administrator. Therefore, the second exclusion criterion has been eliminated, and the computation formulas for estimating the expected number of exceedances have been modified to reflect the number of required monitoring days for the year.

Definition of When the Standard is Attained — EPA is adding Appendix H to 40 CRF Part 50 to explain when the standard is or is not being attained. Certain modifications to the proposal were necessary to accommodate the daily interpretation and the previously mentioned changes in the treatment of missing data. In order to implement the change from an hourly to a daily interpretation, it is necessary to define what is meant by a valid day of ozone data. Such a definition must ensure that a sufficient number of hours of the day have been monitored and that the hourly values in question reflect the time of day when high ozone values are likely to occur. At the same time, this criterion should be relatively easy to implement, it should allow time for routine maintenance, and yet it should protect against high values being ignored merely because not enough hours of the day were measured. Accordingly, a daily maximum hourly average concentration will be considered valid if 75 percent of the hourly values from 9:01 a.m. to 9:00 p.m. (LST) were recorded or if an hourly value above the level of the standard was measured. This validity criterion is intended as a minimum requirement and not as a recommended schedule.

The computation formula for calculating the estimated number of exceedances per year has been modified to correspond to the daily interpretation of the standard. Allowance has also been made for any situation in which the Regional Administator has granted a waiver of the ozone monitoring requirements under the provisions of the recently proposed 40 CFR Part 58 and, therefore, the total number of required monitoring days is less than a full year. The use of the exclusion criterion may result in an underestimate of the probability of an exceedance in some situations but is relatively easy to implement and should suffice to account for the effect of missing data. It should be noted that the formula given in Appendix H is necessary to show attainment. Accounting for missing data can never, however, decrease the number of exceedances, and thus it is possible to establish non-attainment without the use of this equation.

These modifications to Appendix H are intended to simplify somewhat the calculations and to allow for more flexible monitoring schedules. The comments received on Appendix H were varied. A few commenters thought it was too complicated while others suggested even more complex techniques. Most comments were, however, supportive of (or, at least, neutral toward) the proposed approach. One suggestion was to employ a minimum percent completeness requirement, rather than estimating the number of exceedances. The problem with that approach, however, is that it remains unclear as to what should be done with data sets that fail to meet such a completeness requirement.

Some comments discussed the use of 3 years of data. As indicated in the proposal, the choice of a 3-year period represents a compromise between added stability and reasonably current status assessments. Even under the present deterministic form of the standard, attainment designations (e.g., 40 CRF Part 81, Section 107) have been based on more than 1 year. Furthermore, although 3 years are used in estimating the expected number of exceedances under the statistical form of the standard being promulgated, it is still possible to establish nonattainment after one year if, for example, four or more exceedances were reported. Therefore, an upper bound to exceedances during a single year still applies under the new form.

ECONOMIC, ENERGY, AND ENVIRONMENTAL IMPACTS

As has been noted, the Clean Air Act specifically requires that National Ambient Air Quality Standards be based on scientific criteria relating to the level that should be attained to protect public health and welfare adequately. EPA interprets the Act as excluding any consideration of the cost of achieving such a standard in determining the level of the primary standard. However, in compliance with the requirements of Executive Orders 11821 and 11949 and OMB Circular A-107 and with the provisions of the recently issued Executive Order 12044 for rulemaking proceedings that are currently pending, EPA has prepared an analysis of economic impacts associated with efforts to attain this standard.

Ozone air pollution is a pervasive problem throughout the country. Most urban and many rural areas exceed the existing standard. Even with the less stringent standard, most of the major urban areas are not expected to attain the standard in the near term. Control of the organic precursor materials that generate photochemical oxidants is a major effort in this country and a multibillion-dollar program. The existing control program includes measures to reduce organic emissions from automobile and truck exhausts, production of chemical and petroleum products, the dry-cleaning industry, most painting operations (including the automotive industry), and other industrial operations.

Because the attainment problem in most urban areas is so severe, the relaxation of the standard is not expected to change the level of control requirements in the near term. The move to a 0.12 ppm standard will, however, eliminate the theoretical need for major control programs in many rural and wilderness areas that currently exceed the present standard.

With the relaxation of the standard, EPA's economic impact analysis indicates that most urban areas are expected to achieve the standard by 1987. Even with aggressive control programs, however, it will be very difficult for some urban areas to achieve the standard within the next 10 years.

In addition, a document has been prepared assessing the impacts that efforts to attain the standard may have on the nation's energy requirements. This document examines the extent to which ozone precursors will be controlled by recovery of organic materials that would otherwise be emitted to the atmosphere, with resultant energy savings. Furthermore, an additional energy conservation should result in those areas that utilize transportation control measures to reduce precursor emissions by reducing the total number of vehicle-miles travelled. Because of such energy savings, EPA believes that ozone precursor control measures may well lessen the nation's energy requirements.

Finally, environmental impacts associated with control of oxidant precursors have been examined in a document available in docket number OAQPS 78-8. This study indicates that modifying the current standard should have minimal environmental impacts.

Copies of these analyses of the economic, energy, and environmental impacts involved in the revised ozone standard are available from Joseph Padgett at the address given earlier.

REVISIONS TO PART 50 REGULATIONS

In addition to the revised standard, this action necessitates two other revisions to 40 CFR Part 50 as follows:

1. In Appendix D, as well as in the table of sections for Part 50, the title is revised to read as follows: "Appendix D — Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere." The substitution of "ozone" for "photochemical oxidants corrected for interferences due to nitrogen oxides and sulfur dioxide" is a result of the change in the chemical species designation of the standard.

2. Appendix H, "Interpretation of the National Ambient Air Quality Standards for Ozone," is added because additional guidance is necessary to understand the statistical nature of the revised standard.

REVISIONS TO PART 51 REGULATIONS

Elsewhere in this issue of the FEDERAL REGISTER, three revisions to 40 CFR Part 51 are promulgated concurrently with the revision to the photochemical oxidant standard. They are as follows:

1. The term "photochemical oxidants" is changed to "ozone" throughout Part 51.

2. Section 51.14, "Control strategy: Carbon monoxide, hydrocarbons, photochemical oxidants, and nitrogen dioxide," is revised to (a) allow the states to use any of four analytical techniques in the place of Appendix J to calculate the percent hydrocarbon reduction needed to attain the ozone standard, and (b) require that the states consider background ozone concentrations and ozone transport.

3. Appendix J is deleted from Part 51.

FEDERAL REFERENCE METHOD

The measurement principle and calibration procedure applicable to reference methods for measuring ambient ozone concentrations to determine compliance with the standard are not affected by this rulemaking. Elsewhere in this issue of the FEDERAL REGISTER, however, EPA is replacing (superseding) the current calibration procedure with a new, superior, calibration procedure based on ultraviolet photometry. The measurement principle and the current calibration procedure are set forth in Appendix D of 40 CFR Part 50 (as amended in the February 18, 1975, issue of the FEDERAL REGISTER, 40 FR 7042). Reference methods — as well as equivalent methods — for monitoring ozone are designated in accordance with 40 CFR Part 53 (40 FR 7044). A list of all methods designated by EPA as reference or equivalent methods for measuring ozone is available from any EPA regional office, or from EPA, Department E (MD-76), Research Triangle Park, NC 27711.

Dated: January 26, 1979.

DOUGLAS M. COSTLE,

Administrator.

APPENDIX D

Statutory And Regulatory Provisions

National primary and secondary ambient air quality standards for ozone, 40 C.F.R. § 50.9

(a) The level of the national primary and secondary ambient air quality standards for ozone measured by a reference method based on Appendix D to this part and designated in accordance with Part 53 of this chapter, is 0.12 part per million (235 $\mu g/m^3$). The standard is attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 part per million (235 $\mu g/m^3$) is equal to or less than 1, as determined by Appendix H. 44 Fed. Reg. 8220, col. 3 (1979).

* * *

Clean Air Act, § 108, 42 U.S.C. § 7408.

Air quality criteria and control techniques

(a)(2) The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on —

> (A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;
>
> (B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and
>
> (C) any known or anticipated adverse effects on welfare.

CAA § 109, 42 U.S.C. § 7409.

National primary and secondary ambient air quality standards

Protection of public health and welfare

(b)(1) National primary ambient air quality standards, prescribed under subsection (a) of this section shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed under subsection (a) of this section shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutants in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

* * *

Review and revision of criteria and standards; independent scientific review committee; appointment; advisory functions

(d)(1) Not later than December 31, 1980, and at five-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 7408 of this title and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section. The Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.

(2)(A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 7408 of this title and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 7408 of this title and subsection (b) of this section.

(C) Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

CAA § 112, 42 U.S.C. § 7412.

National emissions standards for hazardous air pollutants

List of hazardous air pollutants; emission standards; pollution control techniques

(b)(1)(B) Within 180 days after the inclusion of any air pollutant in such list, the Administrator shall publish proposed regulations establishing emission standards for such pollutant together with a notice of a public hearing within thirty days. Not later than 180 days after such publication, the Administrator shall prescribe an emission standard for such pollutant, unless he finds, on the basis of information presented at such hearings, that such pollutant clearly is not a hazardous air pollutant. The Administrator shall establish any such standard at the level which in his judgment provides an ample margin of safety to protect the public health from such hazardous air pollutant.

* * *

CAA § 172, 42 U.S.C. § 7502.

Nonattainment plan provisions

Expeditious attainment of national ambient air quality standards

(a)(1) The provisions of an applicable implementation plan for a State relating to attainment and maintenance of national ambient air quality standards in any nonattainment area which are required by section 7410(a)(2)(I) of this title as a precondition for the construction or modification of any major stationary source in any such area on or after July 1, 1979, shall provide for attainment of each such national ambient air quality standard in each such area as expeditiously as practicable, but, in the case of national primary ambient air quality standards, not later than December 31, 1982.

(2) In the case of the national primary ambient air quality standard for photochemical oxidants or carbon monoxide (or both) if the State demonstrates to the satisfaction of the Administrator (on or before the time required for submission of such plan) that such attainment is not possible in an area with respect to either or both of such pollutants within the period prior to December 31, 1982, despite the implementation of all reasonably available measures, such provisions shall provide for the attainment of the national primary standard for the pollutant (or pollutants) with respect to which such demonstration is made, as expeditiously as practicable but not later than December 31, 1987.

* * *

CAA § 307, 42 U.S.C. § 7607.

Administrative proceedings and judicial review

(b)(1) A petition for review of action of the Administrator in promulgating any national primary or secondary ambient air quality standard, any emission standard or requirement under section 7412 of this title, any standard of performance or requirement under section 7411 of this title, any standard under section 7521 of this title (other than a standard required to be prescribed under section 7521(b)(1) of this title) any determination under section 7521(b)(5) of this title, any control or prohibition under section 7545 of this title, any standard under section 7571 of this title, any rule issued under section 7413, 7419, or 7420 of this title, or any other nationally applicable regulations promulgated, or final action taken, by the Administrator under this chapter may be filed only in the United States Court of Appeals for the District of Columbia. A petition for review of the Administrator's action in approving or promulgating any implementation plan under section 7410 of this title or section 7411(d) of this title, any order under section 7411(j) of this title, under section 7412(c) of this title, under section 7413(d) of this title, under section 7419 of this title, or under section 7420 of this title, or his action under section 119(c)(2)(A), (B), or (C) (as in effect before August 7, 1977) or under regulations thereunder, or any other final action of the Administrator under this chapter (including any denial or disapproval by the Administrator under subchapter I of this chapter) which is locally or regionally applicable may be filed only in the United States Court of Appeals for the appropriate circuit. Notwithstanding the preceding sentence a petition for review of any action referred to in such sentence may be filed only in the United States Court of Appeals for the District of Columbia if such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination. Any petition for review under this subsection shall be filed within sixty days from the date notice of such promulgation, approval, or action appears in the Federal Register, except that if such petition is based solely on grounds arising after such sixtieth day, then any petition for review under this subsection shall be filed within sixty days after such grounds arise.

(b)(2) Action of the Administrator with respect to which review could have been obtained under paragraph (1) shall not be subject to judicial review in civil or criminal proceedings for enforcement.

* * *

Rulemaking

(d)(1) This subsection applies to —

(A) the promulgation or revision of any national ambient air quality standard under section 7409 of this title,

(B) the promulgation or revision of an implementation plan by the Administrator under section 7410(c) of this title,

(C) the promulgation or revision of any standard of performance under section 7411 of this title or emission standard under section 7412 of this title,

(D) the promulgation or revision of any regulation pertaining to any fuel or fuel additive under section 7545 of this title,

(E) the promulgation or revision of any aircraft emission standard under section 7571 of this title,

(F) promulgation or revision of regulations pertaining to orders for coal conversion under section 7413(d)(5) of this title (but not including orders granting or denying any such orders),

(G) promulgation or revision of regulations pertaining to primary nonferrous smelter orders under section 7419 of this title (but not including the granting or denying of any such order),

(H) promulgation or revision of regulations under subtitle B of subchapter I of this chapter (relating to stratosphere and ozone protection),

(I) promulgation or revision of regulations under subtitle C of subchapter I of this chapter (relating to prevention of significant deterioration of air quality and protection of visibility),

(J) promulgation or revision of regulations under section 7521 of this title and test procedures for new motor vehicles or engines under section 7525 of this title, and the revision of a standard under section 7521(a)(3) of this title,

(K) promulgation or revision of regulations for noncompliance penalties under section 7420 of this title,

(L) promulgation or revision of any regulations promulgated under section 7541 of this title (relating to warranties and compliance by vehicles in actual use),

(M) action of the Administrator under section 7426 of this title (relating to interstate pollution abatement), and

(N) such other actions as the Administrator may determine.

The provisions of section 553 through 557 and section 706 of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies. This subsection shall not apply in the case of any rule or circumstance referred to in subparagraphs (A) or (B) of subsection 553(b) of Title 5.

(2) Not later than the date of proposal of any action to which this subsection applies, the Administrator shall establish a rulemaking docket for such action (hereinafter in this subsection referred to as a "rule"). Whenever a rule applies only within a particular State, a second (identical) docket shall be simultaneously established in the appropriate regional office of the Environmental Protection Agency.

(3) In the case of any rule to which this subsection applies, notice of proposed rulemaking shall be published in the Federal Register, as provided under section 553(b) of Title 5, shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment (hereinafter referred to as the "comment period"). The notice of proposed rulemaking shall also state the docket number, the location or locations of the docket, and the times it will be open to public inspection. The statement of basis and purpose shall include a summary of —

(A) the factual data on which the proposed rule is based;

(B) the methodology used in obtaining the data and in analyzing the data; and

(C) the major legal interpretations and policy considerations underlying the proposed rule.

The statement shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 7409(d) of this title and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences. All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule.

(4)(A) The rulemaking docket required under paragraph (2) shall be open for inspection by the public at reasonable times specified in the notice of proposed rulemaking. Any person may copy documents contained in the docket. The Administrator shall provide copying facilities which may be used at the expense of the person seeking copies, but the Administrator may waive or reduce such expenses in such instances as the public interest requires. Any person may request copies by mail if the person pays the expenses, including personnel costs to do the copying.

(B)(i) Promptly upon receipt by the agency, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period shall be placed in the docket. The transcript of public hearings, if any, on the proposed rule shall also be included in the docket promptly upon receipt from the person who transcribed such hearings. All documents which become available after the proposed rule has been published and which the Administrator determines are of central relevance to the rulemaking shall be placed in the docket as soon as possible after their availability.

(ii) The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

(5) In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submission; (iii) a transcript shall be kept of any oral presentation; and (iv) the Administrator shall keep the record of such proceeding open for thirty days after completion of the proceeding to provide an opportunity for submission or rebuttal and supplementary information.

(6)(A) The promulgated rule shall be accompanied by (i) a statement of basis and purposes like that referred to in paragraph (3) with respect to a proposed rule and (ii) an explanation of the reasons for any major changes in the promulgated rule from the proposed rule.

(B) The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.

(C) The promulgated rule may not be based (in part or whole) on any information or data which has not been placed in the docket as of the date of such promulgation.

(7)(A) The record for judicial review shall consist exclusively of the material referred to in paragraph (3), clause (i) of paragraph (4)(B), and subparagraphs (A) and (B) of paragraph (6).

(B) Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b) of this section). Such reconsideration shall not postpone the effectiveness of the rule. The effectiveness of the rule may be stayed during such reconsideration, however, by the Administrator or the court for a period not to exceed three months.

(8) The sole forum for challenging procedural determinations made by the Administrator under this subsection shall be in the United States court of appeals for the appropriate circuit (as provided in subsection (b) of this section) at the time of the substantive review of the rule. No interlocutory appeal shall be permitted with respect to such procedural determinations. In reviewing alleged procedural errors, the court may invalidate the rule only if the errors were so

serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made.

(9) In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action found to be —

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or

(D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary or capricious, (ii) the requirement of paragraph (7)(B) has been met, and (iii) the condition of the last sentence of paragraph (8) is met.

(10) Each statutory deadline for promulgation of rules to which this subsection applies which requires promulgation less than six months after date of proposal may be extended to not more than six months after date of proposal by the Administrator upon a determination that such extension is necessary to afford the public, and the agency, adequate opportunity to carry out the purposes of this subsection.

(11) The requirements of this subsection shall take effect with respect to any rule the proposal of which occurs after ninety days after August 7, 1977.

Environmental Research, Development and Demonstration Authorization Act of 1978

ERDDAA, 42 U.S.C. § 4365.

Science Advisory Board

Establishment by and advice to Administrator of Environmental Protection Agency

(a) The Administrator of the Environmental Protection Agency shall establish a Science Advisory Board which shall provide such scientific advice as the Administrator requests.

* * *

Proposed environmental criteria document, standard, limitation, or regulation; functions respecting in conjunction with Administrator

(e)(1) The Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the Clean Air Act, the Federal Water Pollution Control Act, the Resource Conservation and Recovery Act of 1976, the Noise Control Act, the Toxic Substances Control Act, or the Safe Drinking Water Act, or under any other authority of the Administrator, is provided to any other Federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based.

(2) The Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession.

Federal Advisory Committee Act, 5 U.S.C. app. § 3. Definitions

For the purposes of this Act —

* * *

(2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is —

(A) established by statute or reorganization plan, or

(B) established or utilized by the President, or

(C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) the advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government.

(3) The term "agency" has the same meaning in section 551(1) of Title 5.

* * *

§ 5. Responsibilities of Congressional committees; review; guidelines

(b) In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall —

> (1) contain a clearly defined purpose for the advisory committee;
>
> (2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;
>
> (3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;
>
> (4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any), the duration of the advisory committee, and the publication of reports and other materials, to the extent that the standing committee determines the provisions of section 10 of this Act to be inadequate; and
>
> (5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

(c) To the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee.

* * *

§10. Advisory committee procedures; meetings; notice, publication in Federal Register; regulations; minutes; certification; annual report; Federal officer or employee, attendance

(a)(1) Each advisory committee meeting shall be open to the public.

(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the Federal Register, and the Director shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

* * *

(d) Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of Title 5. Any such determination shall be in writing and shall contain the reasons for such determination. If such a determination is made, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of Title 5.

Appendix

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No. 81-871

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Petitioners,

v.

ANNE M. GORSUCH, ADMINISTRATOR,
AND ENVIRONMENTAL PROTECTION AGENCY,
Respondents.

SUPPLEMENTAL APPENDIX TO JOINT PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

EDWARD W. WARREN*
ROBERT F. VANVOORHEES
JOHN S. HAHN
KIRKLAND & ELLIS
1776 K Street, N.W.
Washington, D.C. 20006
(202) 857-5000

Counsel for American Petroleum Institute and Member Company Petitioners

BERNARD J. REILLY
1007 Market Street
Wilmington, Delaware 19898

Counsel for E. I. du Pont de Nemours & Company

*Counsel of Record

Of Counsel:
STARK RITCHIE
DAVID T. DEAL
American Petroleum Institute

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SUPPLEMENTAL APPENDIX TO JOINT PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Pursuant to Supreme Court Rule 28.1, a list of the corporate petitioners' parent companies and publicly traded subsidiaries and affiliates is provided as follows.

Conoco Inc.

(Formerly Continental Oil Company)

Parent Company

E. I. du Pont de Nemours & Company *(listed separately below)*

Subsidiaries or Affiliates

Big Sky of Montana Realty, Inc.
Calcasieu Chemical Corporation
Cit-Con Oil Corporation
Conch International Methane Ltd.
Condea Chemie GmbH
Conoco, A.G.
  Petroquimica Espanola, S.A. (PETRESA)
Conoco L.N.G., Inc.
  Conch L.N.G.

- Conoco Management Company
  - Conoco Exploration, Ltd.
- Conoco Mineraloel GmbH
- Conoco Norway Inc.
  - K/s Statfjord Transport A.S.& Co.
  - Statfjord Transport A.S.
- Conoco (U.K.) Limited
  - Benzene Marketing Co. Ltd.
  - Conoco Limited
    - Associated Petroleum Terminals Ltd.
    - Cliffe Storage Ltd.
    - Crude Oil Terminals (Humber) Ltd.
    - Humber Oil Terminals Trustee Ltd.
    - Petroleum Storage Ltd.
    - Warwickshire Oil Storage Ltd.
- K/s Statfjord Transport A.S. & Co.
- Statfjord Transport A.S.
- Consolidation Coal Company
  - Bishop Coal Company
  - Cardinal River Coals, Ltd.
  - Contochu Inc.
  - Harmar Coal Co.
  - Itmann Coal Co.
  - Mathies Coal Co.
  - Neptune Bulk Terminals (Canada) Ltd.
- Continental Carbon Company
  - Carbon Black Espanola, S.A.
  - Compagnie Francaise du Carbon Black, S.A.
  - Continental Columbian Carbon Nederland, N.V.
  - Lucky Continental Carbon Co., Ltd.
  - Toyo Continental Carbon, Ltd.
- Continental Oil Company of Chad
  - SEERAT
- Continental Oil Company of Libya
  - Oasis Oil Co. of Libya, Inc.
- Continental Pipe Line Company
  - Colonial Pipeline Company
  - Lake Charles Pipe Line Company
  - Pioneer Pipe Line Company

- Platte Pipe Line Company
- Seadock, Inc.
- Seaway Pipeline, Inc.
- West Shore Pipe Line Company
- Yellowstone Pipe Line Company

Explorer Pipeline Company
Felix Oil Company
Kettleman North Dome Assoc.
Maritime Protection A/S

- A/S Soties Plass 2
- Maritime Protection (PTE) Ltd.
- Maritime Protection Inc.

Nippon Aluminum Alkyls, Ltd. (NAA)
Nissan-Conoco Corporation (CONSAN)
Oil Shippers Service, Inc.
(OMW) Oberrheinische Mineraloelwerke GmbH
PASA Petroquimica Argentina, S.A.
Petrocokes, Ltd.
Petroleum Terminals, Inc.
San Jacinto Eastern Corporation

- Iricon Agency, Ltd.

Selang Ltd.
Southern Facilities, Inc.
Sulitjelma Elektronikk A/S
The Standard Shale Products Company
Tidelands Royalty Trust

E.I. du Pont de Nemours & Company
Subsidiaries or Affiliates

Conoco Inc. *(listed separately above)*
Remington Arms Company, Inc.

- Industrias Tecnos, S.A.

Airport Limited Partnership
Allied Eneabba Ltd.
Concord Limited Partnership
Desarrollo Quimico Industrial, S.A.
Ducilo S.A.
Du Pont Canada Inc.

- Ducanex Resources Limited

    Twin Peak Resources
  Petrosar Limited
Groupement D'Interet Economique Du Pont de Nemours
  (France) S.A. et Rhone-Poulenc Industries ("GIE")
Mitsuit Fluorochemicals Company, Ltd.
Mitsuit Polychemicals Company, Ltd.
  Bontec Company, Ltd.
  EDOBI
  Hiroshima Sekisui
  Hi-Sheet Industries, Ltd.
  Kyokuto Kobunshi Company, Ltd.
  Kyushu Taiyo Kasei Company, Ltd.
  KZM Company, Ltd.
  Muromachi Company, Ltd.
  Taiyo Kasei Company, Ltd.
PD Magnetics B.V.
Showa Neoprene K.K.
Societe En Nom Collectif Du Pont de Nemours (France)
    S.A. et Rhone-Poulenc Industries ("Butachimie")
Syngas Company
Toyo Products Company, Ltd.
Adela Investment Company S.A.
Derivados Macroquimicos, S.A.
Derivados Sinteticos, S.A. de C.V.
Gemeinnutzige Wohnungsbau GmbH
Halocarburos, S.A. de C.V.
La Domincia, S.A. de C.V.
Nylon de Mexico, S.A.
  Inser, S.A.
  Univex, S.A.
Pigmentos y Productos Quimicos, S.A. de C.V.
Quimica Fluor, S.A. de C.V.
Salgema Industrias Quimicas S.A.
Tetraetilo de Mexico, S.A.

Exxon Corporation
(identified in the court below as Exxon Company, U.S.A., a division of Exxon Corporation)

Subsidiaries or Affiliates

Imperial Oil Limited
Reliance Electric Company
Exxon Pipeline Company

Getty Oil Company
Subsidiaries or Affiliates

Chemplex Company
Chemplex Construction Corp.
Chase Terminal Company
Chase Transportation Company
Entertainment and Sports Programming Network, Inc.
Northern Tier Pipeline Company
Osage Pipe Line Company
Texoma Pipe Line Company
Vancouver Plywood Co., Inc.

Gulf Oil Corporation
Subsidiaries or Affiliates

Gulf Canada Limited
China Gulf Plastics Corporation
Asia Polymer Corporation
Chinhae Chemical Company, Ltd.
Plastgama S.A.
Taiwan VCM Industries Corporation
Bioresearch Center Company, Ltd.
Laurel Pipe Line Company
Platte Pipe Line Company
Venezuela Gulf Refining Company
West Texas Gulf Pipe Line Company
A/S Jargul
A/S Jargul and Co. K/S
AB Djurgardsberg
Adela Investment Company, S.A.
Albert Rose Chemicals, Ltd.

Allied-General Nuclear Services (partnership)
Andogas S.A.
Autobahn-Raststaette Wurenlos Ag.
China Gulf Oil Company Limited
Colonial Pipeline Company
Compagnie D'Investissement Bustibles De
  Reacteurs A Haute Tp.
"Condor" Industria Quimica, S.A.
Delaware Bay Transportation Company
Det Gronlandske Olieaktieselskab
Dixie Pipeline Company
Eastern Venezuela Gas Transport Company
Ethyleen Pijpleiding Maatschappij (Belgium) S.A.
Ethyleen Pijpleiding Maatschappij (Nederland) B.V.
Explorer Pipeline Company
General Atomic Company (partnership)
Gulf Canada Resources Inc.
Gulf Oil Zaire S.A.R.L.
Harshaw-Murata Kabushika Kaisha
Harshaw Galvanotecnia S.A.
Harshaw-Juarez S.A. de C.V.
Harshaw Quimica Ltda.
Hochtemperatur Reaktorbau GMBH
Iranian Oil Participants Limited
Iranian Oil Services (Holdings) Limited
Kuwait Oil Company Limited
London Oil Refining Company Limited
Mainline Pipelines Limited
Midwest Carbide Corporation
Oklahoma Nitrogen Company (partnership)
Pembroke Cracking Company
Petrosil Oil Company Limited
Pol Transport AB
Polyquimicos, S.A.
Raffinerie de Cressier S.A.
Resinas Andinas S.A.
Rio Blanco Oil Shale (partnership)
SARNI S.p.A.

Societe de Combustible Pour Reacteurs A Haute Temperature (Corhat)
Solvent Refined Coal International, Inc.
Sunrise International Company Limited
Svensk Petroleum Administration A.B.
Svensk Petroleum Largring Tre A.B.
Svensk Petroleum Forvalting A.B.
Taita Chemical Company, Ltd.
Taiwan Plasticizer Corporation
Britama Tankers Limited

Grace Petroleum Corporation
Parent Company

W.R. Grace & Co.

Subsidiaries or Affiliates

Axial Basin Ranch Co. (partnership)
Bison Nitrogen Products Co.
Catoleum Catalyst Proprietory Ltd. (Australia)
Chemed Corporation
Colowyo Coal Company (partnership)
DuBois Chemical Italiana S.P.A.
E.T. Beverage Company, Inc.
Emabond, Inc.
Fuji-Davison Chemical, Ltd.
H-G Coal Company (partnership)
Hayden-Gulch West Coal Company (partnership)
J.T. Beverage Inc.
L.C.S. Beverage Company, Inc.
Nippon Belt Kogyo K.K.
Oklahoma Nitrogen Co.
Paramount Coal Co. (partnership)
Productora de Papeles S.A. (Colombia)
Rapoca Energy Co. (partnership)
Rayonese Textile, Inc.
S & H Beverage Company, Inc.
Sea Oil Homco Ltd.
Terry Eagle Coal Company (partnership)
Trinidad Nitrogen Co., Limited (Trinidad and Tobago)

Kerr-McGee Corporation

Subsidiaries or Affiliates

Bikita Minerals (Private) Limited
Brewster Phosphates (partnership)
Crescent Petroleum Company
Downtown Airpark, Inc.
Little Medicine Development Co.
Oklahoma Stations, Inc.
San-Ann Premium Center, Inc.
San-Ann Service, Inc.
Transocean Drilling Company (Bahamas)
Transocean Drilling (Curacao) N.V.
Transshore Drilling Company Limited
Transshore Drilling (Curacao) N.V.
Texoma Pipe Line Company
White Shoal Pipeline Corp.

Mobil Oil Corporation

Parent Company

Mobil Corporation

Subsidiaries or Affiliates

AB Djurgardsberg
Abu Dhabi Petroleum Company Limited
Adria-Wien Pipeline Gesellschaft m.b.H.
AIMCO (ALPHA) Shipping Company
Aircraft Fuel Supply B.V.
Airtankdienst Koln
AK Chemie GmbH
AK Chemie GmbH & Co KG
Akauma Rekisei Kogyo Kabushiki Kaisha
Alexandroupolis Petroleum Installation S.A.
Allied Asphalts Limited
Alpa Alet Ve Dayanikli Tuketim Mamulleri
  Pazarlama A.S.
Altona Petrochemical Company Limited
Alyeska Enterprises, Inc.
Alyeska Pipeline Service Company
Arabian American Oil Company

Arabian International Maritime Company Limited
Arabian International Maritime Company
The Arabian Petroleum Supply Company (S.A.)
Aral Aktiengesellschaft
A/S Fjellvegen
A/S Kongens Plass I
A/S Moretral
Ammenn GmbH
The Associated Octel Company Limited
Associated Octel Company (Plant) Limited
Atlas Sahara S.A.
Australasian Petroleum Company Proprietary Limited
Australian Synthetic Rubber Company Limited
Autobahn-Betriebe Gesellschaft m.b.H.
Aviation Fuel Services Limited
Aygaz Anomim Sirketi
B.V. Beheersmaatschappij MOBEM
Basrah Petroleum Company Limited
Bataan Refining Corporation
Bayerische Erdgasleitung GmbH
Bostadsrattsforeningen Basunen, Malmo
Bostadsrattsforeningen Forarsatet, Orby
Bostadsrattsforeningen Silverskatten, Trelleborg
Bostadsrattsforeningen Skepparegarden, Norrkoping
Brazos Heights Housing Incorporated
Brussels Airfuels Service S.C.
Buffalo River Improvement Corporation
Canner's Steam Company, Incorporated
Cansulex Limited
Canyon Reef Carriers, Inc.
Celmisia Shipping Corporation
Central African Petroleum Refineries (Pvt) Limited
Central Kagaku Kabushiki Kaisha
Changi Airport Fuel Hydrant Installation Pte. Ltd.
Chuo Nenryo Gas Kabushiki Kaisha
Colonial Pipeline Company
Comet-Brennstoffdienst GmbH
Comex-Seal France S.A.
Comex-Seal Guernsey Ltd.

Comex-Seal Limited
Comex-Seal U.K. Limited
Comex-Seal U.S. Corporation
Compagnie Africaine de Transport Cameroun
Compagnie D'Entreposage Communautaire
Compagnie Rhenane de Raffinage
Compagnie Senegalaise des Lubrifiants (C.S.L.)
Compania Colombiana de Empaques Bates, SSA
Compania de Lubricants de Chile Limitada
  (Copec-Mobil Ltda.)
Compania Mexicana de Especialidades Industriales,
  S.A. de C.V.
Consortium Raymond Duez
Cook Inlet Pipe Line Company
Croager Bros. (1962) Limited
Cyprus Petroleum Refinery Limited
D. Muhlenbruch GmbH
D. Muhlenbruch GmbH & Co. KG
Dai Nippon Jushi K.K.
De. Ba. Deposito di Bari S.p.A.
Depot Petrolier de Mourepiane
Depot Petrolier du Gresivaudan
Depots de Petrole Cotiers
Depots Petroliers de La Corse (DPLC)
Deutsche Transalpine Oelleitung GmbH
Dicomi S.r.l.
Dixie Pipeline Company
Drivmedelscentralen AB
Dukhan Services Company
East Japan Oil Development Company Ltd.
Eastern Lease Company Ltd.
Entrepot Petrolier de Chambery
Entrepot Petrolier de Dijon
Deutsche Pentosin — Werke GmbH
Entrepot Petrolier de Mulhouse (E.P.M.)
Entrepot Petrolier de Nancy
Entreprise Jean Lefebvre
Erdgas-Verkaufs-Gesellschaft mbH
Erdoel-Lagergesellschaft mbH

Erdoel-Raffinerie Neustadt GmbH & Co. oHG
Erdoelbetrieb Reitbrook
Erdoelraffinerie Gesellschaft mbH in Liquidation
Etablissments Bouthenet
Etablissements Nicol and Cie
FACEL
Felix Oil Company
Filtroleo-Sociedade Portuguesa de Filtros Lda.
Filtros De Costa Rica S.A.
Finsbury Printing Limited
Fountain Garage (Alfreton Road) Ltd.
Fountain Garage (East Park) Ltd.
Fountain Garage (Leyton) Ltd.
Fountain Garage (Meadowhead) Ltd.
Fountain Garage (Mercury) Ltd.
Fountain Garage (Newbury Park) Ltd.
Fountain Garage (Stirchley) Ltd.
Frome-Broken Hill Company Proprietary Limited
Fruehmesser GmbH
Fuso Operations Kabushiki Kaisha
Futuro Enterprises (Christchurch) Ltd.
Futuro Homes (N.Z.) Ltd.
Gaz Aletleri Anonim Sirketi
Geomines-Caen
Geovexin
Germ Lubricants Limited
Froehmesser Mineraloelhandels GmbH & Co. KG
Ghana Bunkering Services Limited
Goteborgs Branslesortering AB
Groupement Immobilier Petrolier G.I.P.
Groupement Petrolier Aviation G.P.A.
Groupement Petrolier De Brest (GPB)
Handelmaatschappij Hugenholtz & Co. B.V.
H.E. Oils Limited
Heizoel-Handelsgesellschaft mbH
Hellas Gas Storage Company S.A.
Home Counties Petroleum Products Limited
Hormoz Petroleum Company

Hydranten-Betriebs-Gesellschaft, Flughafen
Frankfurt
Iranian Oil Participants Limited
Iranian Oil Services (Holdings) Limited
Iranian Oil Services Limited
Iraq Petroleum Company, Limited
Iraq Petroleum Pensions Limited
Iraq Petroleum Transport Company Limited
Island Exploration Company Proprietary Limited
Japan Airport Fueling Service Co. Limited
Japan Solar Energy Co., Ltd.
J.E.C.O.P.
K. Allan & Company Limited
K.K. Sankyo Plastics
K.K. Toresen
Kanto Kyguns Sekiyu Hambai K.K.
Kanto Oil Pipline Co., Ltd.
Kawasaki Kygnus Sekiyu Hambai Kabushiki Kaisha
Keihin Kygnus Sekiyu Hambai Kabushiki Kaisha
Keiyo Sea-Berth Company, Limited
Kettleman North Dome Association
Klaus Koehn GmbH
Klaus Koehn GmbH & Co. Mineraloel KG
Kobe Port Service Kabushiki Kaisha
Kygnus Ekika Gas Kabushiki Kaisha
Kyokyto Petroleum Services Overseas, Ltd.
Kurt Ammenn GmbH & Co. K.G.
Kygnus Kosan Kabushiki Kaisha
Kygnus Sekiyu Kabushiki Kaisha
Kyokuto Sekiyu Kogyo Kabushiki Kaisha
Les Supermarches De Cote D'Ivoire
Lubricantes del Sur, S.A.
Marceaux & Cie
Matco Tankers (U.K.) Limited
Maury Manufacturing Company, Inc.
Mediterranean Refining Company
Meentzen & Franke GmbH & Co.
Michael Beecham Limited
Mobil Korea Lube Oil Industries Inc.

Mobil Motor Rest AG
Mobil Oil Maroc
Mobil Oil Senegal
Modern Buildings Membranes Ltd.
Mosul Petroleum Company Limited
Motel Rest SA
Motrate Products Limited
Mt. Marrow Blue Metal Quarries Pty.
Ndola Oil Storage Company Limited
Near East Development Corporation
New Zealand Refining Company Limited, The
New Zealand Synthetic Fuels Corp. Ltd.
Nichimo Sekiyu Seisei Kabushiki Kaisha
Nippon Unicar Company Limited
Norddeutsche Erdgas-Aufbereitungs GmbH
Nordic Storage Company Ltd.
Nottingham Gas Limited
N.V. Rotterdam-Rijn Pijpleiding Maatschappij
N.V. Socony-Standard-Vacuum Oil Company
Occidental de Empaques, Ltda.
Octel Associates
Octel S.A.
Oil Kol (Proprietary) Limited
Oil Service Company of Iran (Private Company)
Oldenburgische Erdoel Gesellschaft mit beschrankter Haftung
Olympic Pipe Line Company
Osage Pipe Line Company
P.T. Arun Natural Gas Liquefaction Company
P.T. Stanvac Indonesia
Paloma Pipeline Company
Pars Investment Corporation
Pembalta Gas System No. 1 Ltd.
Pembalta Gas System No. 3 Ltd.
Pembalta Gas System No. 4 Ltd.
Pembalta Gas System No. 5 Ltd.
Pembalta Gas System No. 6 Ltd.
Perrietti Petroli S.p.A.
Petrocab

Petrogas Processing Ltd.
Petroleum Development (Cyprus) Limited
Petroleum Services (Middle East) Limited
Petroleum Tankship Company Inc.
Petromin Lubricating Oil Company
Petromin Lubricating Oil Refining Company
Pipe-Lines de la Pallice
Plegadizos para la Industria S.A.
Poly Oil Chimie (P.O.C.)
Qatar Petroleum Company Limited
Qualbank, Inc.
Ragosine Oil Company Limited
Rainbow Pipe Line Company, Ltd.
Randhurst Corporation
Rhodes Petroleum Installation S.A.
Rivers Court Estates, Limited
Roc Lubricants Limited
Rohel-Aufsuchungs Gesellschaft mbH
Ruhrgas Aktiengesellschaft
S&M Pipeline Limited
S.A.M. Lebreton
Samarco (Alpha) Shipping Company
Samarco (Beta) Shipping Company
Sanwa Kasei Kogyo Kabushiki Kaisha
Sarni S.p.A.
Saudi Can Company, Ltd., The
Saudi Chemical Industries Company Limited
Saudi Arabian Maritime Company
Saudi Maritime Company Ltd.
Saudi, Yanbu Petrochemical Company
Schubert Kommanditgesellschaft
Seal Participants (Holdings) Limited
Segher de Mexico, S.A. de C.V.
Seibu Kygnus Sekiyu Hambai Kabushiki Kaisha
SENERCO
Seram Societa per Azioni (S.p.A.)
Sierra Leone Petroleum Refining Company Limited, The
Societe Anonyme Etablissments Nicol and Cie
Socalor

Societa Italiana per l'Oleodotto Transalpino, S.p.A.
Societe Africaine de Raffinage
Societe Agicole Des Entreprises Petrolieres (S.A.D.E.P.)
Societe Belge de Transport par Pipeline S.A.
Societe Camerounaise des Depots Petroliers (S.C.D.P.)
Societe Civile de Mustapha
Societe Civile Immobiliere Courcelles-Etoile
Societe Civile Immobiliere de Construction de 34 Avenue du General Leclerc a Boissy-St-Leger
Societe Civile Immobiliere de Construction "La Residence Brune"
Societe Civile Immobiliere Kleber-Etoile
Societe Civile Immobiliere La Fontaine Saint Lucien
Societe Civile Immobiliere Mobil
Societe Dahomeenne d'Entreposage de Produits Petroliers
Societe d'Armement Fluvial et Maritime "SOFLUMAR"
Societe de Construction & de Gestion CB 12
Societe de Distribution Castelroussine (SODICA)
Societe de Gaz D'Oceanic (SOGADOC)
Societe de Manutention de Carburants Aviation (S.M.C.A.)
Societe de Manutention de Carburants Aviation Dakar-Yoff
Societe de Manutention de Carburants Aviation de Tahiti (SOMCAT)
Societe d'Entreposage de Bobo-Dioulasso (S.E.B.)
Societe d'Entroposage d'Hydrocarbures de Bingo (SEHBI)
Societe d'Entreposage de San Pedro (SESP)
Societe d'Entreposage Petrolier au Burundi
Societe d'Habitations a Loyer Modere de la Seine Maritime
Societe des Bitumes et Cut-Backs du Cameroun
Societe Des Huiles Lemahieu
Societe de Pipe-Line Sud-Europeen

Societe Gabonaise d'Entreposage de Produits
  Petroliers
Societe Gabonaise de Raffinage
Societe Industrielle des Asphaltes et Petroles
  de Lattaquie (Syrie) S.A.
Societe Ivoirienne de Fabrication de Lubrifiants
  (S.I.F.A.L.)
Societe Ivoirienne de Raffinage
Societe Mauritanienne d'Entreposage de Produits
  Petroliers
Societe Nationale de Raffinage (Sonara)
Societe Novodis
Societe Pizo De Formulation De Lubrifiants (PIZOLUB)
Societe Tahitienne de Depots Petroliers
Societe Tchadienne D'Entreposage de Produits
  Petroliers
Societe Togolaise d'Entreposage (STE)
SONEX
South African Oil Refinery (Proprietary) Limited
South Saskatchewan Pipe Line Company
South West Africa Road Binders (Proprietary)
  Limited
Statfjord Transport A.S.
Sydney Metropolitan Pipeline Pty. Ltd.
Syria Petroleum Company Limited
T.R. Miller Mill Company, Inc.
Tanklagergesellschaft Koln-Bonn
Tecklenburg GmbH
Tecklenburg GmbH & Co.
Texoma Pipe Line Company
Thailand Lubricant Products Limited
Thailand Solvent Products, Ltd.
Thomas Moscrop (Lion Oils) Limited
Thums Long Beach Company
Toa Nenryo Kogyo Kabushiki Kaisha
Tohko Plastics Co., Ltd.
Tonen Energy International Corp.
Tonen Sekiyu Kagaku Kabushiki Kaisha

Tonen Tanker Kabushiki Kaisha
Tonen Technology Kabushiki Kaisha
Total Centrafricaine de Gestion (TOCAGES)
Transalpine Finance Holdings S.A.
Transalpine Oelleitung in Oesterreich Gessellschaft m.b.H.
Trans-Arabian Pipe Line Company
Transgas Umschlags-Lager-Und Transport Gesellschaft MbH
Turkish Petroleum Company Limited
Twifo Oil Plantations Ltd.
UBAG Unterflur Betankungsanlage Flughafen Zurich
United Kingdom Oil Pipelines Limited
W.A.G. Pipeline Pty. Ltd.
Wako Kasei Kabushiki Kaisha
Wakohjushi Kabushiki Kaisha
Werner Weidemann Mineraloelvertrieb G.m.b.H.
West Shore Pipe Line Company
Wolverine Pipe Line Company
Wyco Pipe Line Company
Zaire Services Des Entreprises Petrolieres
Ankara Gaz Satis Anonim Sirketi
ATAS — Anadolu Tasfiyehanesi Anonim Sirketi
Bayerische Mineral-Industrie A.G.
Benoil S.A.
Cercera S.A.
Combustibles Colmeraver
Colombianos Distribuidores de Combustibles, S.A.
Compagnie Immobiliere
Compagnie Regionale de Distribution de Produits Petroliers-C.O.R.E. Dis.
Constructora Calle 7[illegible].A.
CORCOP
C.R.C. Lyon Chauffage
CRCP
Deutsche Mobil Oil Exploration Ireland Ltd.
Emoleum (Asphalts) Limited
Faavang Autoverksted A/S
Imperial Gas Co. of P.R., Inc.

Istanbul Petrol ve Makine Yaglari Limited Sirketi
Les Nouveaux Comptoirs Petroliers
Mobil Ami, S.A.
Mobil Atlas Sociedad Anonima de Capital Variable
Mobil Chemie Belgie N.V. and Mobil Chimie Belge S.A.
Mobil-Comercio, Industria e Servicos Ltda.
Mobil Gaz-Mobil Petrol Gazlari. Anonim Sirketi
Mobil Oil Angola, SARL
Mobil Oil Cameroun
Mobil Oil Cote d'Ivoire
Mobil Oil Dahomey
Mobil Oil Djibouti, S.A.
Mobil Oil Francaise
Mobil Oil Gabon
Mobil Oil Ghana Limited
Mobil Oil Haute Volta
Mobil Oil Holdings S.A.
Mobil Oil Mali
Mobil Oil Mauritanie
Mobil Oil Niger
Mobil Oil Nigeria Limited
Mobil Oil Nord-Africaine
Mobil Oil Philippines Inc.
Mobil Oil Portuguesa, S.A.R.L.
Mobil Oil Rwanda-Burundi (S.A.R.L.)
Mobil Oil Tchad
Mobil Oil Togo
Mobilrex
Mobil Tunisie
Mobil Tyco Solar Energy Corporation
Morem
Petroleum Refineries (Australia) Proprietary Limited
S.A. Mas & Cie
SARL Garage Pineau
S.C.I. DuFonds Du Val
R. Simonnet & CIE
Sociedade Portugal Marrocos SARL

Societe Camerounaise Equatoriale De Fabrication De Lubrifiants "S.C.E.F.L."
Societe Civile Immobiliere du 10 Bd. de la Republique A La Garenne-Colombes
Societe de Maperialx d' Etancheite Pour Le Entreprises (Meple)
Societe de Renovation D'Emballages Metalliques
Societe des Etablissements Goux
Societe Francaise Stoner-Mudge
Societe Nouvelle Raffinerie Meridionale De Ceresines (RMC)
Societe Regionale De Produits Petroliers
SOMODIP
Sonarep (South Africa) (Proprietary) Limited
Station-Service Lunes
Toulouse — Distribution Produits Petroliers
Zaire Mobil Oil
Cartoenvases Valencia, S.A.
Carton de Colombia, S.A.
Carton de Venezuela, S.A.
Cartones Nationales, S.A.
Celulosa y Papel de Columbia, S.A.
Corrugadora de Carton, S.A.
Highgate Associates, Ltd.
Industria de Carbon del Valle Cauca, S.A.
Molinos de Carton y Papel, S.A.
Reforestadora Andina, S.A.
Union Grafica, S.A.
VOSACEC, S.P.A.

Pennzoil Company
Subsidiaries or Affiliates

National Transit Company
The Eureka Pipe Line Company

Shell Oil Company
Parent Companies and Affiliates

Shell Oil Company is affiliated with the Royal Dutch/Shell Group of companies. Of Shell Oil Company's outstanding shares of Common Stock, approximately 69% is owned of record or beneficially by Shell

Petroleum N.V., a Netherlands company. The voting shares of Shell Petroleum N.V. are owned 60% by Royal Dutch Petroleum Company, The Hague, Netherlands, and 40% by The "Shell" Transport and Trading Company, Limited, London, England. Royal Dutch Petroleum Company and The "Shell" Transport and Trading Company, Limited are holding companies which together or directly or indirectly own securities of companies in the Royal Dutch/Shell Group, the members of which are severally engaged throughout the greater part of the world in one or more phases of the oil, chemical, coal, nuclear energy and metal industries.

Standard Oil Company (Indiana)
Subsidiaries or Affiliates

Analog Devices
Chicago Bank of Commerce
Cetus Corporation
Dearborn Park Corporation
Illinois Neighborhood Development Corporation
National Corporation for Housing Partnerships
Semix
Solarex Company

Texaco Inc.
Subsidiaries or Affiliates

Alberta Products Pipe Line Ltd.
Arabian American Oil Company
Associated Octel Company Limited, The
Aviation Fuel Services Ltd.
Boral Limited
New Zealand Refining Company Limited, The
South Africa Oil Refinery (Proprietary) Ltd.
Batangas Land Company Inc.
Changi Airport Fuel Hydrant Installation Pte. Ltd.
Ndola Oil Storage Company Limited
Central African Petroleum Refineries (Private) Ltd.
East African Oil Refineries Limited

H. C. Sleigh Limited
Pakistan Refinery Limited
Societe Malgache de Raffinage
Societe Reunionnaise d'Entreposage (S.R.E.)
Cia. Refinadora Petrolera Santo Domingo Inc.
Deutsche Transalpine Olleitung GmbH
Forenade Svenska Oljeimportorers AB
Frevlig A.G.
Gas Natural Colombiano S.A.
Ghana Bunkering Services Limited
Iranian Oil Participants Limited
Iranian Oil Services (Holdings) Limited
Irish Refining Company Limited
Maghreb Gaz S.A.
Mainline Pipelines Limited
Miland Airport Refueling Services, S.p.A. (MARS)
Mitsui-Texaco Chemicals Co., Ltd.
Montreal Pipe Line Company Limited
N.V. Rotterdam Rijn Pijpleiding Maatschappij
Oberheinische Mineralolwerke G.m.b.H.
Pars Investment Corporation
Pipelines of Puerto Rico, Inc., The
Raffinerie du Sud-Ouest S.A.
Refinery Services Company S.A.
Rheem del Ecuador C.A.
Rhein-Mein Rohrleitungstransportgesellschaft m.b.H.
Saudi International Petroleum Carrier Ltd.
Sierra Leone Petroleum Refining Company Limited, The
Skandinaviska Raffinaderi Aktiebolaget Scanraff
Societa Italiana per l'Oleodotto Transalpino S.p.A.
Societa per Azioni Raffineria Padana Olii Minerali (SARPOM)
Societe Africaine de Raffinage S.A. (SAR)
Societe Anonyme de la Raffinerie des Antilles (SARA)
Societe D'Entreposage de Bobo-Dioulasso
Societe Camerounaise d'Entreposage (SCE)
Societe Dakaroise d'Entreposage S.A. (SDE)
Societe d'Entreposage de San Pedro S.A. (SESP)

Societe d'Entreposage Petrolier au Burundi S.A.R.L. (SEP-BURUNDI)
Societe De Manutention Des Carburants Aviation Dakar-Yoff (SMACADY)
Societe Gabonaise de Raffinage (SOGARA)
Societe Gabonaise d'Entreposage de Produits Petroliers S.A. (SGEPP)
Societe Tchadienne d'Entreposage de Produits Petroliers S.A. (STEPP)
Societe Togolaise d'Entreposage S.A. (STE)
Svensk Petroleum Forvaltning Aktiebolag
Tankanlage AG Ruemlang (TAR)
Texaco Mexicana, S.A.
Transalpine Finance Holdings S.A.
Transalpine Olleitung in Osterreich GmbH
Trinidad Asphalt Holdings Limited
Trinidad Northern Areas Limited
Trinmar Limited
Trintovac Developments Limited
Refineria Texaco de Honduras, S.A.
Texaco Agro-Industrial (Nigeria) Limited
Quimica Industrial "FIDES" S.A.
Texaco Canada Inc.
Public Fuel Transmission Systems Limited
Great Eastern Oil & Import Co. Limited, The
Texaco Norway A/S
Deutsche Texaco Aktiengesellschaft
Texaco Portugal Prospeccaoe Producao, S.A.R.L.
Texaco North Sea Norway A/S
Texaco Gabon
Texaco Togo
Zaire-Texaco S.A.R.L.
Texaco Nigeria Limited
Texaco-Cities Service Pipe Line Company
Tadlaqaz S.A.
American Overseas Petroleum Limited
Bunkerservice Brunsbuttel G.m.b.H.

Societe Ivoirienne De Futs et D'Emballages
(Sifembal) (See Texaco Cote D'Ivoire)
Societe Guineenne De Lubrifiants et D'Emballages
(SOGUILUBE) (See Texaco Africa Ltd.)
Caltex Petroleum Corporation
Australian Lubricanting Oil Refinery Limited
Phoenicia Oil Company S.A.L.
Botany Bay Tanker Company (Australia) Pty. Limited
Sydney Metropolitan Pipeline Pty. Limited
Koa Oil Company, Limited
Mediterranean Refining Company
Nippon Petroleum Refining Company, Ltd.
Tokyo Tanker Company, Limited
Caltex Deutschland G.m.b.H.
Caltex Mediterranean Limited
Condea Chemie G.m.b.H.
Federated Pipe Lines Ltd.
Flexibox G.m.b.H.
LPG de Panama, S.A.
Pembroke Capital Company Inc.
P.T. Caltex Pacific Indonesia
Petrogas, S.A.
Texaco Maroc
Societe Ivoirienne D'Avitaillements Portuaires
(S.I.A.P.)
Societe Ivirienne D'Entrepasage De Produits
Petroliers (S.I.E.P.P.)
Badger Pipe Line Company
Bayonne Industries, Inc.
Canyon Reef Carriers, Inc.
Colonial Pipeline Company
Coltexo Corporation
Dixie Pipeline Company
Explorer Pipeline Company
Felix Oil Company
Kaw Pipe Line Company
Laurel Pipe Line Company

LOCAP Inc.
LOOP Inc.
Olympic Pipe Line Company
Portland Pipe Line Corporation
Texas-New Mexico Pipe Line Company
THUMS Long Beach Company
West Shore Pipe Line Company
Wolverine Pipe Line Company
Wyco Pipe Line Company
Aircraft Fuel Supply B.V.
Airport Refueling Services S.p.A.
Aktiebolaget Svensk Petroleumlagring
United Kingdom Oil Pipelines Limited
Unterflur Betankungsanlage A.G. (UBAG)
West Australian Natural Gas Pty. Limited
Zaire Services des Entreprises Petrolieres (Zaire S.E.P.)
Aktiebolaget Djurgardsberg
Association Petroliere Belge
Aviation Fueling Services, S.A.
Aviation Service Center
Compagnie Entreposage Communautaire
Singapore Refining Company Private Limited
Societe Belge de Transport Par Pipeline S.A.
Societe de Cabotage Petrolier S.A.
Societe du Pipeline Sud-European S.A.
Societe Nationale de Raffinage
Svensk Petroleumadministration AB
Total Centrafricaine de Gestion
Societe Agricole des Enterprises Petrolieres
Union des Raffineurs Belges
Svensk Petroleumlagring Tre Aktienbolag
Societe Cameraunaise des Depots Petroleirs (SCDP)
TNPL
AK Chemie GmbH & Co. KG
Bergemann KG
Braunkohle-Benzin AG
Knoops & Muller Mineralolhandel GmbH

Karlsruhe-Stuttgart Rohrleitung GmbH
Bremer Mineralolhandel GmbH
Dannenberg & Co. Mineralolhandel GmbH
Mdina Weave Ltd.
W. Knierim & Co. Mineralolhandel Gmbh
Boske & Co. Mineralolhandel GmbH
HoeTex Beteiligungsgellschaft mbH
Wichmann Beteiligungsgesellschaft mbH
Caluplast Farbenfabriken Wichmann
Zerssen Mineralolhandel GmbH & Co. GmbH

Witco Chemical Corporation
Subsidiaries or Affiliates

The Baxenden Chemical Company Ltd. (England)
Baxenden Scandinavia ApS. (Denmark)
Bibby Chemicals Limited (England)
Enco Inc.
Isofoam Limited (England)
PASA Petroquimica Argentina S.A.
Witco Chemical Ltd. (Israel)
Surpass Chemicals Limited (Canada)

Respectfully submitted,

EDWARD W. WARREN*
ROBERT F. VANVOORHEES
JOHN S. HAHN
KIRKLAND & ELLIS
1776 K Street, N.W.
Washington, D.C. 20006
(202) 857-5000

Counsel for American Petroleum Institute and Member Company Petitioners

Of Counsel:
STARK RITCHIE
DAVID T. DEAL
American Petroleum Institute

BERNARD J. REILLY
1007 Market Street
Wilmington, Delaware 19898

Counsel for E. I. du Pont de Nemours & Company

November 20, 1981

**Counsel of Record*

Opposition

FILED

FEB 11 1982

ALEXANDER L. STEVAS,
CLERK

Nos. 81-871 and 81-1019

In the Supreme Court of the United States

OCTOBER TERM, 1981

AMERICAN PETROLEUM INSTITUTE, ET AL., PETITIONERS
v.
ANNE M. GORSUCH, ADMINISTRATOR, ENVIRONMENTAL
PROTECTION AGENCY, ET AL.

CITY OF HOUSTON, TEXAS, PETITIONER
v.
ANNE M. GORSUCH, ADMINISTRATOR, ENVIRONMENTAL
PROTECTION AGENCY, ET AL.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

REX E. LEE
Solicitor General

CAROL E. DINKINS
Assistant Attorney General

DONALD W. STEVER
PATRICK J. CAFFERTY
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

WILLIAM A. SULLIVAN
Enforcement Counsel

GERALD K. GLEASON
Assistant General Counsel

DOROTHY E. PATTON
Attorney

Environmental Protection Agency
Washington, D.C. 20460

QUESTIONS PRESENTED

1. Whether the Environmental Protection Agency's failure to make the proposed national ambient air quality standard for ozone available to the Science Advisory Board for its nonbinding opinion, in technical violation of 42 U.S.C. (Supp. III) 4365(e), required a remand under 42 U.S.C. (Supp. III) 7607(d)(8).

2. Whether the court of appeals properly upheld the Administrator's determination that under 42 U.S.C. (Supp. III) 7409, he was required to set the primary standard for ozone based solely on its adverse effects on public health.

3. Whether the delegation of authority from Congress to the Administrator to set air pollution standards based solely on adverse health effects is constitutionally permissible.

4. Whether the Administrator acted arbitrarily in declining to consider special compliance problems alleged to exist in Houston, Texas in setting a national ambient air quality standard for ozone and in devising general strategies for controlling ozone levels.

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In the Supreme Court of the United States

OCTOBER TERM, 1981

No. 81-871

AMERICAN PETROLEUM INSTITUTE, ET AL., PETITIONERS

v.

ANNE M. GORSUCH, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, ET AL.

No. 81-1019

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ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-32a)[1] is not yet reported.

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[1] "Pet. App." refers to the appendix to the petition in No. 81-871.

JURISDICTION

The judgment of the court of appeals was entered on September 3, 1981. The petitions for a writ of certiorari in No. 81-871 and No. 81-1019 were filed on November 10, 1981 and December 1, 1981, respectively. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTES INVOLVED

Sections 108, 109, and 307(d) of the Clean Air Act, 42 U.S.C. (Supp. III) 7408, 7409, and 7607(d), are set forth at Pet. App. 103a-112a. The relevant portions of the Environmental Research, Development, and Demonstration Authorization Act of 1978 ("ERDDAA"), 42 U.S.C. (Supp. III) 4365 *et seq.*, are set forth at Pet. App. 112a-115a.

STATEMENT

1. The overriding goal of the Clean Air Act, 42 U.S.C. (Supp. III) 7401 *et seq.*, is to protect the public's health and welfare by improving the quality of the nation's air. Section 101(b), 42 U.S.C. (Supp. III) 7401(b). A central part of this effort is the establishment of national ambient air quality standards by the Administrator of the Environmental Protection Agency ("EPA") under Section 109 of the Clean Air Act, 42 U.S.C. (Supp. III) 7409, and their implementation through state plans designed to control the local sources of pollution under Section 110 of the Act, 42 U.S.C. (Supp. III) 7410.

The process for establishing these standards is unusually painstaking. Initially, the Administrator must determine for a specific pollutant whether its emissions "in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare." Section 108(a)(1) of the Act, 42 U.S.C. (Supp. III) 7408(a)(1). Subsequently, the Administrator must prepare and issue for such pollutants air quality criteria documents that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare." Section 108(a)(2) of the Act, 42 U.S.C. (Supp. III) 7408(a)(2). This encyclopedic criteria document, which in essence catalogs information concerning the sources and effects of the given pollutant, provides the information upon which the standards for that pollutant will be based. *Ibid.*

Simultaneously with publication of the criteria document, the Administrator must publish proposed primary and secondary ambient air quality standards for the relevant pollutant. Section 109(a)(2) of the Act, 42 U.S.C. (Supp. III) 7409(a)(2). The primary standard is one which "in the judgment of the Administrator," and based on the data in the criteria document and allowing "an adequate margin of safety," is "requisite to protect the public health." Section 109(b)(1) of the Act, 42 U.S.C. (Supp. III) 7409(b)(1). The secondary standard is one that "in the judgment of the Administrator, [and] based on such criteria, is requisite to protect the public welfare."[2] Section 109(b)(2), 42 U.S.C. (Supp. III) 7409(b)(2). Following public comment and hearings, the Administrator is required to promulgate final standards within six months of the proposal. Section 307(d) of the Act, 42 U.S.C. (Supp. III) 7607(d).

To assist in its assessment of the scientific information underlying the national standards, the agency established a Science Advisory Board ("SAB") in January 1974. The subsequent enactment of Section 8 of the Environmental Research, Development, and Demonstration Authorization Act of 1978 ("ERDDAA"), 42 U.S.C. (Supp. III) 4365, established a statutory basis for the SAB and delineated its functions. In accordance with ERDDAA, the Administrator must "make available" to the SAB any "proposed criteria document, standard, limitation, or regulation" under the Clean Air Act and other designated statutes. Section 8(e)(1), 42 U.S.C. (Supp. III) 4365(e)(1). After review, the SAB "may make available to the Administrator * * * its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession." Section 8(e)(2), 42 U.S.C. (Supp. III) 4365(e)(2). Thus, the role of the Board, as its title indicates, is solely as an advisory body and its judgment is in no way binding on the agency.[3]

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[2] Public welfare is defined as including, but not limited to, "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being." Section 302(h), 42 U.S.C. (Supp. III) 7602(h).

2. In February 1979, the Administrator promulgated new primary and secondary national ambient air quality standards for ozone. 44 Fed. Reg. 8202 (Pet. App. 43a-102a). Ozone is a particularly reactive form of oxygen that is far and away the predominant component of a class of air

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[3] Subsequent to the promulgation of the national standard, states are required to submit state implementation plans to EPA for approval. These plans contain emission limitations and other measures necessary to attain and maintain the ambient air quality standards. Primary standards generally are to be attained no later than three years after EPA's approval of the state plan; secondary standards are to be attained within "a reasonable time." Section 110(a)(2)(A) of the Act, 42 U.S.C. (Supp. III) 7410(a)(2)(A). In the 1977 amendments to the Act, Congress recognized that states were having difficulty in attaining the primary standard for photochemical oxidants, which primarily include ozone. Accordingly, Section 172(a)(2) of the Act, 42 U.S.C. (Supp. III) 7502(a)(2), now provides that the states' attainment of the primary standard for ozone may be postponed until December 31, 1987, upon a showing by a specified time that attainment by December 31, 1982, is not possible despite a state's use of "all reasonably available measures."

pollutants, collectively termed photochemical oxidants, which are commonly known as "smog" (*id.* at 45a).

Photochemical oxidants are not emitted directly into the air. Instead, they are the products of a series of complex chemical reactions between nitrogen oxides and numerous reactive organic compounds (termed precursors) in the presence of sunlight. These precursors are in large measure man-made pollutants (Pet. App. 46a).[4] Nitrogen oxides are emitted primarily from electric power plants, gas and oil fired space heaters, and most types of engines (*ibid.*). The principal source of organic compounds are hydrocarbon emissions from automobiles and truck exhausts, chemical plants and other industrial operations, and gasoline vapors (*ibid.*). Thus, the strategy for the control of ozone and other oxidants in urban areas has long been to control the emission of these hydrocarbons.

In humans, ozone is an irritant to the respiratory passageway and lungs (Pet. App. 49a-50a). Exposure to ozone impairs lung functions and causes coughing, wheezing and chest tightness; its effects can be particularly pronounced for people with an existing respiratory illness, such as asthma, chronic bronchitis or emphysema (*id.* at 49a, 85a). Because ozone reactions in humans depend on the dose, exercising individuals—whose bodies deliver more ozone to the pulmonary region—are especially sensitive (*id.* at 85a). In addition, there is evidence that ozone's effects are exacerbated when it is mixed with other pollutants in the ambient air (*id.* at 50a-51a, 90a).

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[4] Although ozone can be produced from chemical reactions between nitrogen oxides and hydrocarbons that are created naturally from vegetation, natural hydrocarbon poses only a negligible potential for ozone formation (1 U.S. Environmental Protection Agency, *Air Quality Criteria for Ozone and Other Photochemical Oxidants* 1-5 (1978) (hereinafter cited as "criteria document").

The process that culminated in the standard that is at issue in this case began in mid-1976 when EPA undertook to revise its original primary and secondary standards for ozone (see 36 Fed. Reg. 8186 (1971)). EPA began by updating its criteria document. The agency released its first external review draft of the new criteria document in September 1977 (42 Fed. Reg. 42372). Shortly thereafter, the Science Advisory Board was convened to review the document (Pet. App. 9a, 21a).

As would be expected in view of the length and complexity of the criteria document, the SAB offered criticisms and proposed changes in portions of the first draft. EPA responded to the SAB's suggestions, as well as to comments it received from the public, in a second external review draft which was completed in February 1978.

The second draft was made available to the public and the Science Advisory Board for comment. The Board met on February 23, 1978, to review this draft (J.A. Exh. 2, at 405-582)[5]. At that meeting Board members expressed their view that, although the Board was recommending additional changes to the second draft, it was in the main responsive to the Board's earlier suggestions and criticisms (*id.* at 411, 491, 506-507, 517). Indeed, one member specifically stated (*id.* at 506-507):

> I think the comments which were furnished last November were very satisfactorily incorporated in each of these two [health effects] chapters, but I think that they represent those that we saw before, as I mentioned at the last meeting, I thought this document was one of the best of the criteria documents. So, I think that in its present form it is quite satisfactory.

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[5] "J.A." refers to the joint appendix filed with the court of appeals in this case.

Due to time constraints, the Board agreed at the conclusion of the meeting to the Chairman's proposal that it not meet again to review another draft of the criteria document, but instead review by mail the important summary and conclusions section of that document (J.A. Exh. 2, at 563-564, 574, 578).[6]

After that section was revised and resubmitted to the individual members of the Board, six of the eleven members submitted votes to accept the criteria document subject to (1) stated reservations and (2) the assumption that the revised summary and conclusions section accurately reflected corresponding changes in the entire document (J.A. 289-310).[7] Concluding from its review of the ballots and from its discussions with individual Board members (see note 5, *supra*) that it had responded appropriately to the Board's comments (*id.* at 1152), EPA then published the criteria document.

The Administrator published his proposed national ambient air quality standards for ozone in June 1978.[8] 43 Fed. Reg. 26962. Specifically, the Administrator proposed to raise the primary standard to 0.10 ppm, but to retain the secondary standard at 0.08 ppm.

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[6] It was agreed that additional chapters would be sent to individual Board members if requested (Pet. App. 81a). Indeed, after that meeting, individual SAB members were contacted by EPA and their further comments and criticisms discussed before incorporating appropriate changes in the document. 44 Fed. Reg. 8212-8213 (1979).

[7] Although the votes to accept the criteria document stated certain reservations, EPA responded to those reservations either by changing the final criteria document or explaining why changes were deemed to be unnecessary. See note 12, *infra*.

[8] The proposed as well as the final standards are for ozone rather than photochemical oxidants. This change merely served to conform the title of the standard to the pollutant that had been used as the yard stick for determining compliance with the original photochemical oxidants standards. As the court of appeals recognized (Pet. App. 17a), only ozone was measured in determining compliance with the original standards.

After the proposal was published, numerous comments were received and four public hearings were held. Again, EPA carefully evaluated the comments (J.A. 1221 *et seq.*) and on January 26, 1979, adopted final primary and secondary standards for ozone at 0.12 ppm (Pet. App. 43a).

Considering both the studies cited and discussed in the criteria document and the comments received during the comment period, the Administrator concluded that "the most probable level for adverse health effects in sensitive persons, as well as in healthier (less sensitive) persons who are exercising vigorously, falls in the range of 0.15-0.25 ppm" (Pet App. 89a).[9] The Administrator also considered several other factors affecting his judgment as to an adequate margin of safety. These included the increased effects caused by pollutant interactions, animal studies showing that ozone exposure caused reduced resistance to infection, inconclusive studies indicating human effect levels as low as 0.10 ppm, and recently discovered calibration errors in some of the experiments which may have caused them to overstate the ozone concentrations upon which the probable health effects level was based (*id.* at 89a-92a). Based on all of these considerations, the Administrator set the primary standard at 0.12 ppm. Although this standard allowed a narrower margin of safety than the proposed standard, the Administrator thought that it was both "necessary" to protect the public health and "sufficiently prudent unless and until further studies demonstrate reason to doubt that it adequately protects public health" (Pet. App. 92a).

In addition to the final ozone standards, the Administrator also promulgated final regulations concerning methods for determining the amount of hydrocarbon reduction necessary to meet those standards. 44 Fed. Reg. 8234, 8237 (1979). These regulations allow a state to choose any one of four air pollution models to demonstrate compliance with the ozone standards. Each of the four models is based on the scientifically-accepted theory that reductions in hydrocarbon precursor emissions will reduce the amount of ozone in the ambient air. 44 Fed. Reg. 8235 (1979).

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[9] A summary of the results of the studies regarding health effects appears in the preamble to the final regulations (Pet. App. 84a).

3. The court of appeals, in all respects relevant to the petitions in this case, unanimously upheld the ozone standards (Pet. App. 1a-32a). Initially, the court held that in setting the ozone standard the Administrator properly limited his consideration to the adverse health effects of ozone (*id.* at 14a-15a). In this regard the court relied heavily on its earlier decision in *Lead Industries Association* v. *EPA*, 647 F. 2d 1130, cert. denied, 449 U.S. 1042 (1980), in which the court concluded that Section 109 of the Act precluded the Administrator from considering costs or technological feasibility in setting the national standards (Pet. App. 14a-15a). The court also upheld the 0.12 standard as being fully supported by the record (*id.* at 15a-16a). In addition, the court found ample support for the Administrator's decision to promulgate models for demonstrating compliance with the ozone standards based on reductions in hydrocarbon levels (*id.* at 17a).

There were several procedural issues decided by the court of appeals, but the only one raised by the petitioners here involved the failure of the EPA to make the proposed ozone standard (as opposed to the criteria document) available to the Science Advisory Board. The Court concluded that Section 8(e) of the ERDDAA, 42 U.S.C. (Supp. III) 4365(e), did require the agency to make the standard available to the Board for advice and comment (Pet. App. 22a-23a). However, it found that this failure in the circumstances of this case did not create "a substantial likelihood that the rule would have been significantly changed" as required for reversal of a final standard under Section 307(d)(8) and (9)(D), 42 U.S.C. (Supp. III) 7607(d)(8) and (9)(D) ((Pet. App. 22a-23a).

ARGUMENT

1. Petitioners in No. 81-871[10] (Pet. 13-18) first argue that the court of appeals erred in not rejecting the final ozone standard once it determined that EPA had violated Section 8(e) of the ERDDAA, 42 U.S.C. (Supp. III) 4365(e), by not submitting the proposed standard to the Science Advisory Board. The court's decision that the error was harmless in this case, however, is a proper application of the relevant statute governing judicial review of significant agency rulemaking in the Clean Air Act. Moreover, in light of the decision of the court of appeals, the agency's error is unlikely to recur and, accordingly, further review of the decision by this Court is not warranted.

The proper standard for determining whether the agency's error in this rulemaking proceeding requires reversal is set forth in Section 307(d)(9)(D) of the Act, 42 U.S.C. (Supp. III) 7607(d)(9)(D). That section allows reversal for procedural errors only if they are "so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made."[11] This narrow standard of review reflects Congress's intent that major regulations promulgated under the Clean Air Act not be reversed for insubstantial procedural mistakes that are not likely to affect the final result. H.R. Rep. No. 95-294, 95th Cong., 1st Sess. 322 (1977).[12]

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[10] Petitioner City of Houston "concurs with the petition" (81-1019 Pet. 13 n.4) in No. 81-871 as to the issues raised therein and in addition raises its own issues for review (see pages 16-18, *infra*).

[11] This language actually is found in Section 307(d)(8) of the Act, 42 U.S.C. (Supp. III) 7607(d)(8), but is expressly incorporated in the Section 307(d)(9)(D) standard of review. Petitioner vaguely suggests (81-871 Pet. 17) that the narrow standard of review does not apply to the failure to comply with ERDDAA because the first sentence in Section 307(d)(8) refers to "procedural determinations made by the Administrator under this subsection." But this limitation does not

EPA's technical failure to comply with Section 8(e) of ERDDAA is the archetypal procedural error covered by Section 307(d)(8) and (9)(D). Pursuant to ERDDAA the agency had solicited and received substantial input from the Science Advisory Board as to "the adequacy and reliability of the technical basis for rules and regulations." H.R. Rep. No. 95-722, 95th Cong., 1st Sess. 16 (1977). As part of the process in reaching a final standard, the Administrator responded carefully to the Board's comments.[13] Thus, as the

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apply to the general standard of review provision in Section 307(d)(9)(D) which applies the harmless error rule to any "procedure required by law."

Petitioners (81-871 Pet. 17) also assert without any support that ERDDAA is not a procedural requirement within the meaning of Section 307(d)(8) and (9)(D). But in light of the limited role the SAB performs in the decision process, it is clear that the requirements of ERDDAA are procedural.

[12] Indeed, the wisdom of this rule is well illustrated in this case. Promulgation of the rule in early 1979 triggered the revision of many state implementation plans to meet the new ozone standards. Those efforts have required substantial commitments of resources to meet the substantive and procedural requirements of Section 110(a)(1) and, where applicable, Sections 171-178 of the Act, 42 U.S.C. (Supp. III) 7410(a)(1) *et seq.*, 7501-7508. Moreover, numerous private and public decisions have been made based on the ozone standard as promulgated. For a court, two and one-half years after the rule is announced, to suspend the rule and remand to the Administrator so that an advisory board can insert its non-binding opinion into the record would be needlessly wasteful and disruptive. By enacting Section 307(d)(8) and (9)(D) Congress protected against just such a result.

[13] See pages 6-7, *supra*. The assertion (81-871 Pet. 11 n.23) that EPA "fail[ed] to respond to the [SAB's] comments on the draft criteria document" is grossly misleading. The only authority petitioners have ever cited for this proposition is a list of items which they consider to have been inadequately addressed. The comments of individual Board

court of appeals correctly noted (Pet. App. 23a): "[b]ecause any SAB review of the standard would have involved review of the criteria document, i.e., the scientific and technical basis for the [ozone] standard, we cannot hold that the standard would likely have been significantly changed had it been submitted to the Board."

In any event, the error in not submitting the final standard was committed because the agency, pressed for time, did not interpret Section 8(e) of ERDDAA as requiring submission of the proposed standard in light of the prior, extensive review of the criteria document by the SAB. The court of appeals has now made clear that the agency must make proposed standards available to the SAB and there is no reason to assume that the agency will fail to do so in the future. Thus, the issue is clearly not one appropriate for this Court's discretionary review.

2a. Petitioners next argue (81-871 Pet. 18-23) that Section 109 of the Clean Air Act, 42 U.S.C. (Supp. III) 7409, should be interpreted as implicitly containing substantive limits based on the attainability and costs of compliance with the Administrator's national standards. In this regard petitioners place heavy reliance on this Court's decision in *Industrial Union Department* v. *American Petroleum Institute*, 448 U.S. 607 (1980).

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members (see page 8, *supra*) and the Board's ultimate acceptance of the document demonstrate that the agency was hardly unresponsive to comments. In fact, EPA responded appropriately to all comments made by the SAB as well as all comments submitted by the public, including petitioners. Some of those responses appear in the administrative record in documents IIA-G-1 and IIA-G-2, a two-volume set consisting of more than 300 pages; after the February, 1978, SAB meeting (pages 6-7, *supra*) other responses were incorporated into the criteria document, where appropriate, after discussions with individual Board members. 44 Fed. Reg. 8212-8213 (1979).

The Administrator and the court of appeals both recognized that in enacting Section 109 Congress had as its sole concern the protection of public health (Pet. App. 16a). Congress simply did not give the Administrator discretion to consider cost or technical feasibility in setting ambient air standards. Neither Section 108, which specifies the factual criteria upon which the ambient standards are to be based, nor Section 109, which contains the legal test which they must meet, discusses or otherwise suggests any consideration of cost or technical feasibility. See *Lead Industries Association* v. *EPA, supra*, 647 F. 2d at 1149. Moreover, the Senate Report on the 1970 amendments states (S. Rep. No. 91-1196, 91st Cong., 2d Sess. 2-3 (1970)):

> In the Committee discussions, considerable concern was expressed regarding the use of the concept of technical feasibility as the basis of ambient air standards. The Committee determined that 1) the health of people is more important than the question of whether the early achievement of ambient air quality standards protective of health is technically feasible; and, 2) the growth of pollution load in many areas, even with application of available technology, would still be deleterious to public health.
>
> Therefore, the Committee determined that existing sources of pollutants either should meet the standard of the law or be closed down * * *.

See also *Lead Industries Association* v. *EPA, supra*, 647 F. 2d at 1149-1150. The court of appeals thus was completely faithful to the language and intent of Congress in holding that the Administrator properly limited his consideration to the adverse health effects caused by ozone and a reasonable margin of safety in setting the final national standard.[14]

Petitioners' attempt (81-871 Pet. 20-23) to compare this case to *Industrial Union Department* v. *American Petroleum Institute, supra*, is misguided. Initially, the statutory schemes are totally different. The divergent language that Congress employed in OSHA and the Clean Air Act reflects the distinctive and different roles played by OSHA's "occupational safety and health standards" and the Clean Air Act's "ambient air quality standards." The OSHA standards are directly applicable to each industrial employer subject to the standards, and they are directly enforced by federal officials (29 U.S.C. 653(a)(2), 659). In contrast, the development of ambient air quality standards under the Clean Air Act is only the first step in a federal-state scheme, in which EPA defines the level of air quality "requisite to protect the public health," but leaves primarily to the states the attainment and maintenance of that level. See generally *Train* v. *Natural Resources Defense Council, Inc.*, 421 U.S. 60 (1975). Unlike the OSHA scheme, in which the Secretary of Labor must consider feasibility in arriving at a standard, the Clean Air Act requires the Administrator to specify health-protective levels without regard to the economic or technological feasibility of compliance. See S. Rep. No. 91-1196, 91st Cong., 2d Sess. 2-3 (1970), quoted in *Union Electric Co.* v. *EPA*, 427 U.S. 246, 259 (1976).

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[14] Costs and other practical factors may be considered in developing state implementation plans, so long as the plans provide for timely attainment of the ambient standards. *Union Electric Co.* v. *EPA*, 427 U.S. 246, 266 (1976). In short, while Section 109 mandates that the ambient standards themselves be based only on health considerations, Section 110 provides some latitude for the consideration of practical factors in the development of specific measures to attain the standards.

Moreover, remaining problems caused by the difficulty of attaining standards can be resolved by "Congress, the only institution with the authority to remedy the problem," *Lead Industries Association* v. *EPA*, *supra*, 647 F. 2d at 1150. See, *e.g.*, *TVA* v. *Hill*, 437 U.S. 153 (1978); *City of Santa Rosa* v. *EPA*, 534 F. 2d 150 (9th Cir.), cert. dismissed *sub nom. California* v. *EPA*, 429 U.S. 952 (1976). Indeed, Congress has recognized its responsibility in this regard. For example, some states experienced difficulties in attaining the primary standard for photochemical oxidants. As noted above, Congress acted to ease the problem in 1977, *not* by changing the basis on which such standards are to be set but by providing for an extended period of time (until 1987) for attainment. Section 172(a), 42 U.S.C. (Supp. III) 7502(a). In addition, the current Congress is actively considering new amendments to the Clean Air Act.

Moreover, the nature of the administrative decisions involved are completely different. In the *Industrial Union Department* case, a plurality of this Court held that the Secretary failed to make a finding of significant risk of harm and instead set a standard based solely on a series of presumptions. Here, on the other hand, the Administrator specifically found from the medical evidence that it was probable that sensitive people would suffer adverse health effects in the range of 0.15-0.25 ppm (Pet. App. 89a) and that there was a "real possibility of significant human adverse health effects below 0.15 ppm" (*id.* at 92a). The Administrator therefore set the standard at 0.12 to assure a margin of safety (*ibid.*). Thus, the Administrator made exactly the kind of finding this Court found missing in *Industrial Union Department*, and the court of appeals found the Administrator's conclusions fully supported by the record.

b. Petitioners argue (81-871 Pet. 22-23) alternatively that if the Administrator and court of appeals have properly interpreted this statute, then it constitutes an unconstitutional delegation of authority by Congress to the Administrator. This argument lacks merit because Congress carefully delimited the Administrator's discretion.

National ambient air quality standards are to be based only on the scientific evidence contained in the criteria document required by Section 108 of the Act, 42 U.S.C.

(Supp. III) 7408; the rulemaking generally must conform to the demanding procedures contained in Section 307(d) of the Act, 42 U.S.C. (Supp. III) 7607(d); and primary standard must be reasonably designed to protect public health with no more than an adequate margin of safety under Section 109(b)(1) of the Act, 42 U.S.C. (Supp. III) 7409(b)(1); S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970).[15] Such a limited grant of authority in the context of a statute in which Congress has with "clarity" made the "hard choice[]" that protection of public health should be the sole criterion for decision (*Industrial Union Department* v. *American Petroleum Institute*, 448 U.S. 607, 687 (1980) (Rehnquist, J., concurring); *American Textile Manufacturers Institute, Inc.* v. *Donovan*, No. 79-1429 (June 17, 1981), slip op. 3-4 (Rehnquist, J., dissenting))[16] cannot seriously be compared to the "delegation running riot" that was declared impermissible by this Court in the cases cited by petitioners. *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495, 553 (1935) (Cardozo, J., concurring).

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[15] Further, in recognizing that national standards will not necessarily protect people dependent on controlled environments such as intensive care units and nurseries, S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970), the legislative history of the 1970 amendments limits the Administrator to protecting people in the course of their ordinary activities. Congress did not intend the standards to protect people in purely hypothetical or extreme situations. The legislative history also directs that "particularly sensitive citizens such as bronchial asthmatics and emphysematics" should be protected, but limits the Administrator to protection of a "representative sample" of such persons and not the single most sensitive person within the sensitive population. H.R. Rep. No. 95-294, 95th Cong., 1st Sess. 50 (1977). Similarly, the goal of ensuring that the public is protected from "*adverse* effects on the health," S. Rep. No. 91-1196, *supra*, at 10 (emphasis added), restrains the Administrator from using detectable but medically insignificant effects to set standards.

[16] In disregarding these factors, petitioners imply that Section 109 must permit consideration of *non-health* factors to pass muster constitutionally. Congress, of course, has power to choose which factors to include or exclude in delegating authority to an agency, and it has done so in Section 109 by limiting the Administrator to consideration of health factors in the first step of the statutory scheme. Wisely or not, that decision obviously limits the Administrator's discretion. Even as to the health factors to be considered, Congress has further narrowed his discretion as we demonstrate above.

3a. Petitioner City of Houston raises (81-1019 Pet. 13-21) two additional issues. First, it asserts that the statute should require the Administrator to consider the city's peculiar difficulty in attaining the 0.12 ppm standard. This problem, which is regarded by Houston alone as serious enough to bring to the Court's attention, hardly is of sufficient general significance to warrant review by this Court. Moreover, the court of appeals clearly was correct that it is wholly inconsistent with the concept of a national standard to require the Administrator to tailor such a standard to meet regional or local exigencies (Pet. App. 16a); *Natural Resources Defense Council, Inc.* v. *EPA*, 656 F. 2d 768 (D.C. Cir. 1981).[17]

b. Petitioner City of Houston also argues (81-1019 Pet. 17-21) that the Administrator erred by not examining exactly how the ozone control strategy would work in Houston. Specifically, petitioner argues that relying on reductions in hydrocarbon emissions to attain the ozone standard is arbitrary because reductions in hydrocarbon emissions in the Houston area have allegedly not resulted in corresponding reductions in ozone. But, as the court of appeals noted (Pet. App. 16a-17a), "control of ozone by reduction of hydrocarbon [emission] levels is an established methodology" and the only study in the administrative record on which Houston relies "was considered by EPA and rejected on several grounds which undercut the reliability of its conclusions."[18] Thus the court of appeals properly rejected this parochial claim.

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[17] The City of Houston implies (81-1019 Pet. 14 n.7) that rare exceedances of the ozone standard caused by natural conditions, such as the intrusion of stratospheric ozone, demonstrate that the ozone standard is unattainable and unreasonable. This implication is both wrong and irrelevant. It is wrong because states may disregard exceedances of national standards caused by natural occurrences for purposes of determining whether the standards are attained. 40 C.F.R. 51.12(d). It is irrelevant because the fact that a natural occurrence rather than man-made pollution causes an exceedance of a standard does not mean that the resulting level of that pollutant is "healthy." Moroever, no one claims that EPA has set the standards at a level lower than routine natural background levels

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[18] Houston relies (81-1091 Pet. 18-19 n.15) on post-promulgation materials that are not part of the administrative records. Such materials may, of course, be submitted to the Administrator at any time in support of petitions to revise the regulations. Cf. *Oljato Chapter of Navajo Tribe* v. *Train*, 515 F. 2d 654, 666 (D.C. Cir. 1975).

Houston also raises a constitutional argument for the first time in this Court. Houston argues (81-1019 Pet. 16-17) that the ozone standard is so harsh that it constitutes a "taking" of property rights. This argument is frivolous. Property owners have no constitutional right to use their property in a manner which will harm public health and, in any event, Houston has utterly failed to supply any facts upon which a "taking" finding could be based. See, *e.g.*, *Hodel* v. *Virginia Surface Mining & Reclamation Association*, No. 79-1538 (June 15, 1981) ("taking" analyses are essentially "ad hoc factual inquiries").

CONCLUSION

The petitions for a writ of certiorari should be denied.

Respectfully submitted.

REX E. LEE
Solicitor General

CAROL E. DINKINS
Assistant Attorney General

DONALD W. STEVER
PATRICK J. CAFFERTY
Attorneys

WILLIAM A. SULLIVAN
Enforcement Counsel

GERALD K. GLEASON
Assistant General Counsel

DOROTHY E. PATTON
Attorney
Environmental Protection Agency

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Petitioners,

v.

ANNE M. GORSUCH, ADMINISTRATOR,
AND ENVIRONMENTAL PROTECTION AGENCY,
Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

PETITIONERS' JOINT REPLY BRIEF IN SUPPORT OF PETITION FOR CERTIORARI

EDWARD W. WARREN*
ROBERT F. VANVOORHEES
JOHN S. HAHN
KIRKLAND & ELLIS
1776 K Street, N.W.
Washington, D.C. 20006
(202) 857-5000

Counsel for American Petroleum Institute and Member Company Petitioners

JOHN H. PICKERING
WILLIAM H. LEWIS, JR.
DAVID R. JOHNSON
WILMER, CUTLER & PICKERING
1666 K Street, N.W.
Washington, D.C. 20006

Counsel for Chemical Manufacturers Association

**Counsel of Record*

Of Counsel:
STARK RITCHIE
DAVID T. DEAL
American Petroleum Institute

EDMUND B. FROST
Chemical Manufacturers Association

February 22, 1982

Additional counsel listed inside cover.

GERALD L. BALILES
  ATTORNEY GENERAL OF VIRGINIA
ROGER L. CHAFFE
  ASSISTANT ATTORNEY GENERAL
  101 North 8th Street
  Richmond, Virginia 23219

Counsel for the Commonwealth
  of Virginia, ex rel. the State
  Air Pollution Control Board

BERNARD J. REILLY
  1007 Market Street
  Wilmington, Delaware 19898

Counsel for E. I. du Pont
  de Nemours & Company

WILKES C. ROBINSON
J. SCOTT BROWN
  GULF COAST & GREAT PLAINS
  LEGAL FOUNDATION
  127 West 10th Street
  Room 1022
  Kansas City, Missouri 64105

Counsel for St. Louis Regional
  Commerce and Growth Association

JAN ERIC CARTWRIGHT
  ATTORNEY GENERAL OF OKLAHOMA
NEAL LEADER
  ASSISTANT ATTORNEY GENERAL
  112 State Capitol Building
  Oklahoma City, Oklahoma 73105

Counsel for State of Oklahoma

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PETITIONERS' JOINT REPLY BRIEF IN SUPPORT OF PETITION FOR CERTIORARI

Respondents ("EPA") offer fundamentally inconsistent arguments in an effort to belittle the significance of this case. On one hand, EPA characterizes its violation of the Environmental Research, Development, and Demonstration Authorization Act of 1978 ("ERDDAA") as "technical", arguing that this "procedural" error is excusable because it "is unlikely to recur" and because remand "would be needlessly wasteful and disruptive." EPA Brief ("EPA Br.") 10-12, n.12. Yet when seeking to avoid the constitutional delegation issue, EPA characterizes the same procedural requirements as "demanding" (*id.* 16) to support its argument that "Congress carefully delimited the Administrator's discretion." *Id.* 15. As we will show, these contradictory EPA arguments cannot mask the importance of the holding below, which would seriously undermine judicial review of administrative action, remove all effective constraints on EPA's discretion in setting ambient air quality standards, and needlessly cost the Nation additional billions of dollars annually.

ARGUMENT

A. EPA Cannot Obscure the Far-Reaching Implications of the Decision Below for Judicial Review of Administrative Actions.

Starting from the proposition that the SAB's judgment "is in no way binding on the agency,"[1] EPA proceeds to the *non sequitur* that the requirements of ERDDAA can be ignored when EPA is "pressed for time" or when compliance is otherwise inconvenient. EPA Br. 4, 12.[2] EPA then promises that "the agency's error is unlikely to recur" because "there is no reason to assume that the agency will fail" again to comply with ERDDAA. EPA Br. 10-12. But despite EPA's efforts to paint the decision below as *sui generis,* it has far-reaching implications for judicial review of cases arising under the Clean Air Act. Pet. 14-16.

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[1] Throughout EPA denigrates the expanded advisory role that Congress established for the SAB. EPA Br. 4, 11, n.12. *Compare to* Petition for Certiorari ("Pet.") 4-5. But it would have been pointless to require EPA to submit every proposed rule to the SAB if Congress had not intended for EPA at a minimum to consider and respond to the Board's advice. *See* Pet. 14 n.29. In view of that requirement, it was hardly a "technical" violation (EPA Br. I, 11) here when EPA denied the SAB any opportunity to review the proposed standard.

EPA's references to SAB review of the draft criteria document (EPA Br. 6-7, 11-12, n.13), in addition to being overstated (*see* Joint Reply Brief in the court of appeals 11-17), are entirely beside the point. Any suggestion that the SAB would have had nothing to say about the scientific basis for the proposed ozone standard was forcefully contradicted in Congressional testimony by SAB Chairman Whittenberger shortly after the standard was promulgated. *Id.* 16-17.

[2] The more than *seven months* between the time EPA published its proposal and the time it promulgated the final standard (EPA Br. 7-8) belie EPA's claim that it was pressed for time. During this period the SAB easily could have reviewed EPA's proposal. Pet. 14.

The court's sweeping interpretation of § 307(d)(8) of the Clean Air Act, 42 U.S.C. § 7607(d)(8), treats as excusable "procedural" error Agency actions that violate the mandatory requirements of another statute expressly designed to improve the scientific quality of EPA standards. Pet. 4-5. The court required nothing of EPA, not even a statement — much less a showing — that SAB review of the proposed standard would have made no difference.[3] Rather, the court's action was based on bare speculation that the Agency would not have been forced to change its mind in the face of a critical SAB review.[4] So construed, § 307(d)(8) would excuse virtually any error in the standard-setting process, no matter how significant, without requiring any support for a conclusion that compliance with the law would not have changed the result reached by the agency.

This is not the first time EPA has cited time constraints and a promise that "the issue presented will not recur" as reasons why this Court should not review a case involving §§ 307(d)(8) & (9). In *United States Steel Corp.* v. *EPA*, 444 U.S. 1035, 1038 (1980), three Justices of the Court voted to grant certiorari because, in part, of their concern that applying §§ 307(d)(8) & (9) could have the "effect of establishing two Administrative Procedure Acts, one for the EPA and one for all other agencies" (dissenting op. of Justice Rehnquist). The decision below goes even further, because it broadly construes § 307(d)(8) to excuse violations of statutes other than the Clean Air Act and would turn the test of § 307(d)(8) into a virtually irrebuttable presumption against reversal on procedural grounds.[5] Because this result was never intended by Congress (Pet. 16), the writ should be granted.

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[3] Precisely such a showing has been required in other cases. *See* Braniff Airways, Inc. v. CAB, 379 F.2d 453, 467 (D.C. Cir. 1967). The need for such a showing here is especially compelling, for if the SAB had followed the Regulatory Analysis Review Group in recommending a higher standard, EPA likely would have been constrained to follow suit. Pet. 8, 15-16.

[4] EPA implies that SAB review of the proposed standard would have been irrelevant, based on a closely-cropped and misleading quotation of the SAB's Dr. McCarroll. EPA Br. 6. Immediately following the passage quoted by EPA, however, Dr. McCarroll concluded that "there is no demonstrable health effect before .25 ppm" (Joint Appendix Ex. 2 in the Court of Appeals 507), and later explained that "[o]viously, from what I have said here today and what else I have written, I think that *one could well justify a more relaxed standard.*" *Id.* 543 (emphasis added). These and similar conclusions by other Board members were directly contrary to EPA's proposal, and provide the most plausible explanation why EPA refused to submit the proposal to the SAB. Pet. 7.

B. The Constraints Posited by EPA Do Not Cure the Standardless Delegation Approved by the Court Below.

EPA seeks to skirt petitioners' delegation argument by positing constraints supposedly showing that "Congress carefully delimited the Administrator's discretion." EPA Br. 15.[6] But the constraints offered by EPA are chimerical.

EPA argues that "the rulemaking generally must conform to the *demanding* procedures contained in § 307(d) of the Act" (EPA Br. 16) (emphasis added), notwithstanding EPA's earlier claim that § 307(d)(8) excuses it from the even more "demanding" requirements of ERDDAA in this case. EPA Br. 10-12.[7]

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[5] The court below acknowledged as much by refusing even to consider whether EPA had violated other statutory requirements, on the ground that those violations also would be excused by § 307(d)(8). Petitioners' Appendix ("Pet. App.") 25a.

[6] Nowhere does EPA respond to petitioners' argument that § 109 of the Clean Air Act readily can be construed so as to limit EPA's discretion. *See* Pet. 21-23.

[7] The "demanding" procedures required by § 307(d) are those typically used for notice-and comment rulemaking. *Compare* 42 U.S.C. § 7607(d) with the rulemaking provisions of the Administrative Procedure Act, 5 U.S.C. § 553.

Such elastic provisions, that supposedly can be dismissed as inconsequential whenever they are violated, cannot at the same time serve as rigid bounds on the Agency's discretion. Moreover, even if these procedural requirements were enforceable, they alone would not confine the Agency's substantive discretion within constitutional limits.

EPA also argues that standards must "be based *only* on the scientific evidence contained in the criteria document." EPA Br. 15 (emphasis added). Besides the fact that the standard here was *not* based *only* on the criteria document,[8] this requirement imposes no identifiable limits regarding how lax or stringent the standard should be.

Finally, EPA now argues that "the primary standard must be *reasonably* designed to protect public health with *no more than* an adequate margin of safety." EPA Br. 16 (emphasis added). But nowhere did EPA or the court below apply or give any substance to this test, much less establish a basis for judging the adequacy of a margin of safety. *See* Pet. 18-19.

As interpreted by EPA and the court below, § 109 of the Clean Air Act simply does not provide meaningful guidance as to the *degree* to which an ozone standard should protect health, or even as to how to decide that question. *See* Pet. 18-19. It is not sufficient to say, as EPA does, that Congress "made the 'hard choice[]' that protection of public health should be the sole criterion for decision" (EPA Br. 16), when the entire question in setting a standard concerns *how much* protection to provide. Without some guidance from Congress regarding the extent to which "the law of diminishing returns" should be applied in setting ambient air quality standards,[9] EPA, even more than OSHA in the *Benzene* case, would have power to impose "enormous costs that might produce little, if any, discernible benefit." *Industrial Union Dept., AFL-CIO* v. *American Petroleum Institute,* 448 U.S. 607, 686, 645 (1980). That, of course, is exactly what happened in this case.

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[8] The court below found that EPA based the ozone standard not only on the criteria document, but on a variety of other evidence as well. Pet. App. 11a.

[9] Nowhere does EPA contest the fact that it implicitly invoked "the law of diminishing returns" in rejecting an ozone standard of zero, and in setting emission standards for the more serious "hazardous" pollutants under § 112 of the Clean Air Act, 42 U.S.C. § 7412. *See* Pet. 23, n.46.

C. Far from Being "Needlessly Wasteful and Disruptive" as EPA Argues, Remand Here Could Save the Nation Billions of Dollars Annually Without Jeopardizing Public Health.

EPA argues that the court below correctly excused EPA's violation of ERDDAA because remanding the standard would be "needlessly wasteful and disruptive," requiring, among other things, revision of state implementation plans. EPA Br. 11, n.12. EPA's concern for waste and disruption is misplaced. Revising state implementation plans to account for a new standard would be a trivial — and for many states a welcome — inconvenience compared to the substantial "waste and disruption" that will result from permitting EPA to issue rules like the needlessly stringent and costly ozone standard at issue here.[10] Compliance costs for the standard chosen by EPA will exceed $12 billion *annually,* which is $3 billion more *annually* than the cost of the less stringent standard recommended by the Regulatory Analysis Review Group. Pet. 8. Over and above its high total and incremental costs for the public, EPA's standard will require construction bans that restrict industrial growth in many parts of the country, while making no significant contribution to public health. *Id.*

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[10] Under § 110 of the Clean Air Act, 42 U.S.C. § 7410, states must prepare and enforce state implementation plans containing whatever control measures are necessary to attain the standard. Pet. 3. The presence of states as co-petitioners and *amici* here demonstrates that they are more than willing to revise their implementation plans if the standard is relaxed. Moreover, states that fail to attain the standard by the end of 1982 will be required to revise their implementation plans anyway. *See* EPA Br. 4 n.3.

Accordingly, the enormous consequences of the decision below, for the economy and for the establishment of procedural and substantive constraints governing other cases, make this a compelling case for review by the Court.

CONCLUSION

For the reasons stated in this Brief and in the Petition for Certiorari, the writ should be granted.

Respectfully submitted,

Edward W. Warren*
Robert F. VanVoorhees
John S. Hahn
Kirkland & Ellis
1776 K Street, N.W.
Washington, D.C. 20006
(202) 857-5000
Counsel for American Petroleum Institute and Member Company Petitioners

John H. Pickering
William H. Lewis, Jr.
David R. Johnson
Wilmer, Cutler & Pickering
1666 K Street, N.W.
Washington, D.C. 20006
Counsel for Chemical Manufacturers Association

Gerald L. Baliles
Attorney General of Virginia
Roger L. Chaffe
Assistant Attorney General
101 North 8th Street
Richmond, Virginia 23219
Counsel for the Commonwealth of Virginia, ex rel. the State Air Pollution Control Board

Of Counsel:
Stark Ritchie
David T. Deal
American Petroleum Institute

Edmund B. Frost
Chemical Manufacturers Association

February 22, 1982

**Counsel of Record*

BERNARD J. REILLY
1007 Market Street
Wilmington, Delaware 19898
Counsel for E. I. du Pont
de Nemours & Company

WILKES C. ROBINSON
J. SCOTT BROWN
GULF COAST & GREAT PLAINS
LEGAL FOUNDATION
127 West 10th Street
Room 1022
Kansas City, Missouri 64105
Counsel for St. Louis Regional
Commerce and Growth Association

JAN ERIC CARTWRIGHT
ATTORNEY GENERAL OF OKLAHOMA
NEAL LEADER
ASSISTANT ATTORNEY GENERAL
112 State Capitol Building
Oklahoma City, Oklahoma 73105
Counsel for State of Oklahoma